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AIDS AND THE VETERANS' ADMINISTRATION

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS UNITED STATES SENATE

ONE HUNDREDTH CONGRESS

FIRST SESSION

JUNE 24, 1987

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CONTENTS

JUNE 24, 1987

Page
AIDS and the Veterans' Administration 1

OPENING STATEMENTS

Chairman Cranston 2
Senator Murkowski 4
Senator Thurmond 1

WITNESSES

Clinton, Dr. J. Jarrett, Deputy Assistant Secretary of Defense (Professional Affairs and Quality Assurance), Office of the Assistant Secretary of Defense for Health Affairs, accompanied by Col. William Bancroft, Medical Corps, U.S. Army 10
  Prepared statement of Dr. Clinton 91
Crow, Dr. W.A., III, Associate Chief of Staff for Ambulatory Services, Houston Veterans' Administration Medical Center 54
Curran, Dr. James W., Director, AIDS Program, Center for Infectious Diseases, Centers for Disease Control, Public Health Service, U.S. Department of Health and Human Services 12
  Prepared statement of Dr. Curran 117
Foley, Mary E., Chairman, Cabinet on Economic and General Welfare, American Nurses' Association, accompanied by Thomas Nickels, Director, Congressional and Agency Relations; and Donna Richardson, Assistant Director, Congressional and Agency Relations 44
  Prepared statement of Ms. Foley 153
Gordon, Dr. Earl, Chief of Staff, West Los Angeles Veterans' Administration Medical Center 54
Gronvall, Dr. John A., Chief Medical Director, Department of Medicine and Surgery, Veterans' Administration, accompanied by Dr. Howard Cohn, Deputy Assistant Chief Medical Director for Clinical Affairs; Robert Lindsey, Director of Operations; Dr. Susan Mather, Chief of Pulmonary and Infectious Diseases; Dr. Richard Greene, Assistant Chief Medical Director for Research and Development; and Ralph Ibson, Deputy Assistant General Counsel 7
  Prepared statement of Dr. Gronvall 81
McFarren, Ann E., Executive Director, AIDS Action Council 48
  Prepared statement of Ms. McFarren 177
Myers, Dr. Woodrow A., Jr., State Health Commissioner, State of Indiana, and President, Association of State and Territorial Health Officials 46
  Prepared statement of Dr. Myers 166
Schafer, Dr. Paul W., Executive Director, National Association of VA Physicians 49
  Prepared statement of Dr. Schafer 186
Simberkoff, Dr. Michael, Chief, Infectious Disease Section, New York City Veterans' Administration Medical Center 55

APPENDIX

Written committee questions and the responses:
  Chairman Cranston to:
    Dr. J. Jarrett Clinton 197

Written committee questions and the responses—Continued

Page
Chairman Cranston to—Continued
    Dr. James W. Curran 210
    Ann E. McFarren 213
    Veterans' Administration 215
Senator Graham to the Veterans' Administration 229
Senator Murkowski to the Veterans' Administration 230
Senator Simpson to the Veterans' Administration 241

AIDS AND THE VETERANS' ADMINISTRATION

WEDNESDAY, JUNE 24, 1987

U.S. SENATE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

The committee met, pursuant to notice, at 9:36 a.m., in room SR-418, Russell Senate Office Building, Hon. Alan Cranston (chairman of the committee) presiding.

Present: Senators Cranston, DeConcini, Graham, Murkowski, Thurmond, and Stafford.

OPENING STATEMENT OF SENATOR THURMOND

Senator THURMOND. Good morning. The committee will come to order. The Chairman will be here in a few minutes.

I have another appointment, so I will have to go. So, I wanted to make a statement first. It is a pleasure to be here today to receive testimony on one of the most perplexing issues facing our country today—Acquired Immune Deficiency Syndrome. Mr. Chairman, this is an issue which requires our very careful and thoughtful attention, and I want to commend the Chairman for scheduling these hearings.

President Reagan has recently declared that AIDS is the No. 1 public health problem of this Nation. The facts bear this out. Over 33,000 cases of AIDS have been reported in the United States. Some 20,000 individuals have died from this deadly disease since it was first reported in 1981.

At least 1.5 million Americans have been infected with the virus. It is alarming that AIDS may soon become the tenth leading cause of death in this country.

The Surgeon General, C. Everett Koop, in his recent report on AIDS stated that, by the end of 1991—just 3½ years from now—an estimated 270,000 cases of AIDS will have occurred, with 179,000 related deaths. These numbers are disturbing. In an effort to address this problem, I was pleased last week to join with several of my Republican colleagues in introducing the Omnibus Acquired Immune Deficiency Syndrome Act of 1987, many features of which were included in legislation recently considered by the Labor and Human Resources Committee, of which I am a member.

Mr. Chairman, there is no escaping the sad fact that AIDS has also had an adverse impact upon the veteran population. As members of this committee, we must ensure that the VA Medical Centers provide an adequate level of care to AIDS patients. At the same time, we must not ignore other non-AIDS related health-care problems.

To summarize, any legislation from this committee must be carefully drafted to appropriately address this complex issue. Mr. Chairman, because of prior commitments, I will not be able to remain for the full hearing. I will look forward to reviewing the testimony of the distinguished witnesses.

I want to welcome all the distinguished witnesses here today, and I will read your testimony. I am sorry that I cannot remain. Thank you very much.

We will be in recess until the chairman arrives.

[Whereupon, at 9:39 a.m., a brief recess was held.]

[The committee reconvened at 9:45 a.m.]

OPENING STATEMENT OF CHAIRMAN CRANSTON

Chairman **Cranston**. The hearing will come to order. I apologize for the slight lateness of our beginning. I am pleased to welcome all of you to the Senate Veterans' Affairs Committee's first hearing focusing exclusively on AIDS.

AIDS is clearly this Nation's and, very likely, the world's greatest health threat. Six years ago AIDS was unknown to the United States. Today, tens of thousands of Americans are suffering from illnesses caused by the HIV infection. AIDS has already claimed the lives of more than 20,000 Americans and an estimated 1.5 to 2 million more have been infected with the HIV virus. A majority of them will likely develop AIDS within the next 10 years. The count worldwide is equally alarming; between 5 and 10 million people may be carrying the virus.

We are in the midst of a terrible human tragedy. Unfortunately, in addition to the AIDS epidemic, we are also facing an epidemic of fear, fear that has resulted from a lack of information and education about AIDS. We also face the potential of a great epidemic of distrust, distrust that may result from policies that are being proposed for mass testing of individuals for the virus without the informed consent of those individuals. We must do everything to find a treatment, vaccine, and cure for AIDS as rapidly as possible.

We must be equally vigilant in our efforts to prevent further spread of the HIV infection. That means a major commitment to AIDS public information and prevention programs.

I am proud to have been at the forefront of congressional efforts over the past 6 years to provide the resources needed for such research, development, public information, and prevention programs. We have a long way to go, but we are on the right track, I believe, in terms of congressional initiatives. As we develop AIDS programs and efforts, we must listen to our public health experts and scientists, establish policies that are based on their recommendations, and not succumb to the panic and prejudice that so often accompany the debate on AIDS. Sound public health concepts—not ideology or partisan politics—must guide our decisions and policies regarding AIDS.

You will hear today from some important public health experts and learn what the VA—which operates the largest health-care system in the United States—is doing and can do to help stop the AIDS epidemic. The American people are looking to the Federal Government to help them understand the disease, to separate fact from fiction, to help quell the hysteria. Unfortunately, presidential leadership has been sorely lacking on this issue and still is.

Nearly 5 years after the Congress—over administration objections—first started force-funding various Federal efforts to combat AIDS, we still did not have a national policy or strategy for dealing with it. Indeed, the President made his first major speech on AIDS only a month ago, but no presidential action has been taken. Instead, Reagan appointees who are not doctors and who are not experts in this field are loudly advocating points of view at odds with the views of the President's own top health advisers. The results have been drift, disarray, and dismay. Thus, it becomes especially important that Federal agencies and officials with pertinent missions themselves take on a leadership role.

About 6 percent of all AIDS cases in the United States are being cared for by the VA. The VA has treated more than 2,000 people with AIDS since 1981 and will see about 1,300 this year alone. If the AIDS caseload continues at the same rate, the VA may see 14,000 AIDS patients by 1991.

Earlier this year, our committee included in its fiscal year 1988 budget recommendations $47.5 million in additional AIDS treatment funding for VA Medical Centers. Although this additional funding was not expressly assumed in the budget resolution that has emerged from conference, I will continue working to add it to the VA's fiscal year 1988 appropriations.

I was pleased to learn a few days ago that the VA, as I had been urging, recently provided $4 million in supplemental funding support to seven of its medical centers with the largest numbers of AIDS cases and will be pursuing this morning what basis will be used for making AIDS adjustments in the fiscal year 1988 allocations to VA Medical Centers. As I indicated at our May 21 hearing, I believe it is essential that VA Medical Centers provide comprehensive education, counseling, and other prevention activities for VA health-care workers and patients and a comprehensive public education program for all VA beneficiaries and their families.

The Surgeon General, Dr. C. Everett Koop, has done an outstanding job in his 1986 report on AIDS. I am pleased that the VA has made efforts to distribute this document. I believe that the VA must dramatically expand those efforts, and I will pursue that goal vigorously.

On the issue of testing, I oppose President Reagan's proposal to require routine testing of all veterans being admitted to VA hospitals. The VA sees about 1.4 million hospital inpatients each year. Thus, testing would cost at least $21 million and probably much more at commercial rates and with the necessary attendant counseling. The majority of VA patients are elderly men at very low risk for AIDS.

The National Academy of Sciences and the Surgeon General, as well as the American Medical Association, have already stated that mandatory testing of patients admitted to hospitals is not appropriate. Not only would such widespread testing be cost prohibitive and unmanageable, to use the words of the Surgeon General, but it is virtually impossible to guarantee confidentiality of medical records in a VA or in any hospital. Hence, individuals may be deterred from seeking medical help because of the fear of the information about their medical status will leak out.

Most public health experts urge that high risk and other individuals be encouraged to take the HIV test, be fully counseled about the pros and cons of having the test performed, and be given the opportunity to provide specific informed, voluntary consent before being tested.

The issues here boil down to whether patients will be given that opportunity or whether they will be required to take the test as a condition of being furnished care or whether their blood will be tested without their knowledge and consent. In seeking the cooperation of people with AIDS or ARC and those who have been infected with the HIV virus, the use of coercion or deception would seem to be a totally counterproductive approach.

Finally, with regard to research, the VA has been in the forefront of many biomedical breakthroughs. I believe that it can play a significant role in basic and clinical research on AIDS. It is essential, however, that Federal agencies supporting research on AIDS—the VA, HHS, and the Department of Defense—cooperate and coordinate their efforts to the maximum degree possible. The VA is an important component in our war against AIDS. To do its job effectively, it must be equipped with the resources it needs to perform these vital lifesaving and lifeprolonging activities.

The committee is very interested in the ideas and views of all of those appearing before us today. We thank them for their help on these vitally important matters. Frank, do you have an opening statement?

OPENING STATEMENT OF SENATOR MURKOWSKI

Senator MURKOWSKI. Thank you, Mr. Chairman. I do. I wish the panelists good morning. I am pleased that we have such a distinguished group of experts here today to consider one of our Nation's foremost and serious health problems.

AIDS may certainly be a threat to our Nation. AIDS is estimated, as I understand it, to infect 1 out of every 30 males in the country. I have a difficult time accepting that type of statistic. I gather, however, that in many cases it is dormant; but it is certainly a sobering statistic. The consequences for our society are significant. We must initiate an appropriate procedure. I don't know that we know necessarily what that procedure should be. There is a substantial energy outflow that is out there, but is it appropriate and is it directed in the most effective manner?

Certainly as the Nation's largest health-care provider, the VA must play an important role in the fight against AIDS. However, their role cannot be considered in isolation. It must, in fact, be part of a national response. Such a response requires a clearly defined and articulated policy that has the support of the medical profession, policymaking officials and the American people.

I don't know, Alan, but I was somewhat frustrated in the debate that we had on the floor on AIDS because it was a debate based on a response from our colleagues to want to do something. Of course, we can always throw money at problems, but the question is: Is it the most efficient way to respond to the threat that is upon us? Obviously, that is what we are looking for.

Certainly a policy which identifies research, prevention, and treatment goals and sets in motion a mechanism to conquer this epidemic is our objective. This policy must be a compassionate one that recognizes the needs and hopes of persons with AIDS, but equally important, one that addresses the threat this disease poses to all Americans, present and future.

We also have the concern for individual rights and so forth. I believe that through the wisdom and collective efforts of those in the medical and related professions, we can find the answers. Now, I was shocked to learn some time ago that in one of the New York Veterans' hospitals, nearly one-third of the inpatients and outpatients were veterans receiving treatment for AIDS. The costs of this treatment is extraordinary. It is staggering in the sense of recognizing that we are not set up to provide for the costs of that type of care.

I think you would agree that it is not our intention to delude ourselves into believing that an answer to the AIDS mystery is going to be found overnight. We need only to look at records with regard to cancer. We have prime examples of effective treatment but ultimately a cure for those complex diseases are often slow and disappointing. Although we have made important strides after many years of a serious commitment to cancer research, there is much that we simply do not know and the research must continue. It is imperative that we develop and implement a definite plan, a plan for prevention and control of the disease.

Now, mandatory testing has been proposed as one method. There has been a lot of discussion on this issue. Various persuasive insights and arguments have been made on both sides of the issue, but the critical policy question remains to be answered. I, for one, am at this time reluctant to support such testing until we are satisfied that testing indeed is the most effective way to control and prevent the spread of AIDS. We look forward to your testimony specifically on those questions.

For example, who will have access to the test results? For what specific purpose will the test results be used? What are the confidentiality rights of a patient? What is the cost? Would our limited resources be better directed toward research, education, and treatment?

The question that I have, and I think it is a primary one, is that I assume that when veterans go into a hospital, as a matter of routine, there is a blood test that occurs—not specifically for the purpose of identifying AIDS. What further effort is needed to test a patient for the AIDS virus?

The obvious question is: Is that appropriate? We do it for other reasons and obviously for the ability to treat the patient for other diseases. It is a matter of routine. I would appreciate it if you would reflect in your testimony on this question because I think our concern is one of confidentiality and the rights of the patients.

There has been much criticism of the President's recommendation that the veterans be among those that are mandatorily tested in the inpatient/outpatient care. Recognizing that the President has control over a relatively limited number of health-care beneficiaries—the Department of Defense, the VA, the Federal institutions, and others—I think it would be unfair to suggest that he is picking out the veterans and not other groups. He is picking out those groups that are under Federal control, and the question is a legitimate one. That is, whether veterans should or shouldn't be included. As I said, I am reluctant to support it at this time, but I would appreciate your specific recommendations. We have an item in The New York Times today: Mandatory Tests for AIDS Virus Opposed by Doctors at the VA.

So, we will look forward to hearing your testimony. I think that the hearing today and the witnesses that are with us will shed much needed light on this subject and give not only this committee but the Senate a better opportunity to address what action should be taken. Thank you, Mr. Chairman.

Chairman CRANSTON. Thank you very much. Bob, do you have a statement?

Senator STAFFORD. Mr. Chairman, I have no opening statement. I am here to hear what the witnesses have to say.

Chairman CRANSTON. Thank you. Dennis.

Senator DECONCINI. No, I have no opening statement. Thank you, Mr. Chairman.

Chairman CRANSTON. We are starting out with a panel of Administration witnesses, consisting of Dr. John A. Gronvall, Chief Medical Director, Veterans' Administration, accompanied by Dr. Howard Cohn, Deputy Assistant Chief Medical Director for Clinical Affairs; Mr. Robert Lindsey, Director of Operations; Dr. Susan Mather, Chief of Pulmonary and Infectious Diseases; Dr. Richard Greene, Assistant Chief Medical Director for Research and Development; and Mr. Ralph Ibson, Deputy Assistant General Counsel; Dr. Jarrett Clinton, Deputy Assistant Secretary of Defense (Health Affairs) for Professional Affairs and Quality Assurance, accompanied by Col. William Bancroft, U.S. Army; and finally, Dr. James Curran, Atlanta, Georgia, Director of the AIDS Program, Center for Infectious Diseases, Center for Disease Control.

I have a great many questions that I want to pursue, and I know the others on the committee may well have the same number of questions in their minds. So, I would appreciate it very much if you would keep your answers as brief and to the point as possible and amplify in writing where needed.

I will be moving back and forth among the witnesses to ask questions on various subjects. John, would you now make your statement, please?

STATEMENT OF DR. JOHN A. GRONVALL, CHIEF MEDICAL DIRECTOR, DEPARTMENT OF MEDICINE AND SURGERY, VETERANS' ADMINISTRATION, ACCOMPANIED BY DR. HOWARD COHN, DEPUTY ASSISTANT CHIEF MEDICAL DIRECTOR FOR CLINICAL AFFAIRS; ROBERT LINDSEY, DIRECTOR OF OPERATIONS; DR. SUSAN MATHER, CHIEF OF PULMONARY AND INFECTIOUS DISEASES; DR. RICHARD GREENE, ASSISTANT CHIEF MEDICAL DIRECTOR FOR RESEARCH AND DEVELOPMENT; AND RALPH IBSON, DEPUTY ASSISTANT GENERAL COUNSEL

Dr. GRONVALL. Thank you very much, Mr. Chairman. We have prepared a detailed statement, which I would request be made a part of the hearing record.

Chairman CRANSTON. It will be.

Dr. GRONVALL. And in the interest of time, I will make a summary opening statement. This disease, AIDS, a devastating disease, is emerging as the first major lethal worldwide epidemic or pandemic of the second half of the 20th century. The Veterans' Administration health-care system is a very major part of the resources that this country has to care for individuals suffering from AIDS and also to participate in research that will bring this disease under control.

From September 1983 to May 1987, 2,014 cases of full-blown AIDS have been reported in the VA.

Senator MURKOWSKI. Doctor, would you give that figure again?

Dr. GRONVALL. 2,014 cases have been documented in the VA of full-blown AIDS.

Senator MURKOWSKI. Would you define "full-blown" vis-a-vis "half-blown"?

Dr. GRONVALL. Yes, sir. The use of the term "full blown AIDS" means that the person is infected with the AIDS virus and has developed the active disease. The person's immune response system has been reduced, and so the person suffers from a complication, either an infectious disease or the development of one of the cancers.

Senator MURKOWSKI. I don't want to prolong this, but I made a statement that it is estimated that 1 out of every 30 males in this country is affected with the AIDS virus now. You can comment on the accuracy or the inaccuracy, but I assume my figure is not "full-blown."

Dr. GRONVALL. Your figure would apply to the number of people who have been infected with the virus, not the number of people who have gone on to develop the active disease state. And my figure of 2,014 cases are the cases that have the active disease.

Senator DECONCINI. Would the ranking member yield? I don't want to prolong the debate, but just for educational purposes, can you determine that someone is infected with the virus but does not have the so-called "full-blown" or the actual disease. Is that right?

Dr. GRONVALL. Yes.

Senator DECONCINI. Now, someone who is infected with the virus who doesn't have the actual disease, what is the prognosis or there is any on how many of those become full-blown and get the disease?

Maybe that is in your statement.

Dr. **Gronvall**. Yes, but this is a good place to comment on it. There are many individuals who have been infected; laboratory tests can show that they have developed antibodies to the AIDS virus, but they have no symptoms. It is not now possible to say with precision how many of those individuals go on subsequently to develop the active disease.

Senator **DeConcini**. You just don't know yet?

Dr. **Gronvall**. There are estimates that place that at something like one-third to as high as 75 or 80 percent. Our experience is growing, and so that is an answer that is evolving based on our experience.

Senator **DeConcini**. Thank you, Doctor.

Senator **Stafford**. Doctor, could you supply us for the record, if you can't do it now, the age groups involved in full-blown and otherwise infected veterans who have AIDS?

Dr. **Gronvall**. Yes. We would be pleased to supply the description of veterans who have the disease with those kind of categorizations.

Senator **Stafford**. We would appreciate it. Thank you.

[Subsequently, the Veterans' Administration furnished the following information:]

Information on ages of VA patients with AIDS is not available on all patients in the AIDS registry. However, a manual compilation of the approximately 1,000 on which age and race or ethnic group data is available is being done and should be available by August 1, 1987. A survey of 90 patients discharged from VA medical centers in 1986 showed the average age to be 41.2 years with a range of 24 to 67. We will provide the compilation of information to the Committee when it is available.

Senator **Murkowski**. I just have a question. Is 1 out of 30 realistic, or am I all wet?

Dr. **Gronvall**. I think Dr. Curran from CDC is the best person to speak to that question.

Senator **Murkowski**. How many males are there in the country? About 100 million?

Dr. **Gronvall**. 120 million approximately.

Senator **Murkowski**. 120 million? How many of those are believed to be infected.

Dr. **Curran**. The 1 in 30 estimate was attributed to me via several newspapers, and it came from a presentation that I made at the AIDS Conference here in Washington. What I was doing was discussing the prevalence of infection in the United States, how many people are infected with the virus; and the discussion was that there had been ½ a million to 4 million. The Public Health Service has estimated that there are 1.5 million; and I was pointing out that 1.5 million is a large number indeed because, if they are distributed like the reported cases of AIDS—by sex and by age—that would mean that most of these 1.5 million people are men between the ages of 20 and 50.

And in fact, if there are 1.5 million infected Americans, that means that 1 in 30 men between the ages of 20 and 50 in the United States are infected with the virus. This number, of course, would be a great deal higher in New York and in California and other areas.

Chairman **Cranston**. That is a quite different statistic.

Senator **Murkowski**. Well, is it that different?

Dr. **Curran**. It is between the ages of 20 and 50, excluding people younger than 20 and older than 50.

Senator **Murkowski**. In that range it would be, in your opinion, accurate?

Dr. **Curran**. I think that is pretty close, and it would be much higher in some areas.

Senator **Murkowski**. So, you can assume then that these people are infected, have been infected through blood or sexual relationships. Is that correct?

Dr. **Curran**. The studies that have been done among people identified as infected would suggest that the majority have been infected—the vast majority—through sexual contact or intravenous drug abuse.

Senator **Murkowski**. Thank you. Thank you, Mr. Chairman.

Chairman **Cranston**. John, your 5 minutes are now up. [Laughter.]

You may have a fresh start.

Dr. **Gronvall**. All right, fine. The impact of this disease in the VA is heaviest on the east and west coasts, but actually 111 of our medical centers have had at least one case. As we look to the future, we have projected that we might have treated something like 14,000 cases by 1991.

Treatment of AIDS in our hospitals is complex and requires a very dedicated team of medical specialists and subspecialists and it also places an enormous burden on our nurses, social workers, and chaplains. We have tried to estimate the cost of AIDS care. In 1985, our estimate was that it was costing about $38,000 per year in the VA for each AIDS patient.

More recently, that figure has gone down as we have gained more experience, and we have had patients in the hospital shorter lengths of time and made less use of our intensive care units. At the present time, we are estimating something like $20,000 per year per patient; but because the total number of patients has increased remarkably, we have made supplemental funding allocations to our medical centers that have treated more than 15 cases.

And again, as we look toward the future, new drugs or new treatments that are developed might remarkably change the cost experience, either up or down. The advent of a new treatment that was itself very expensive could increase the cost of care or, more hopefully, an effective treatment or, better yet, prevention could of course remarkably reduce the cost.

Mr. Chairman, during the May 21 hearing, we discussed your suggestion that we expand our education efforts, particularly for high risk groups. I am pleased to tell you that we agree with this suggestion, and we are now developing an educational program on AIDS that will be a routine part of all of our substance abuse programs.

We are working closely with other Federal agencies. That collaboration includes the Department of Defense, the Department of Health and Human Services, Centers for Disease Control; and we participate actively on an intergovernmental task force on AIDS health-care delivery.

In regard to research, I should just note that the Veterans' Administration is engaged in the entire spectrum of research on

AIDS. We are conducting basic science studies on the mechanism of action of the AIDS virus infection. We are engaged in clinical trials of drug treatment. And one study is particularly important to take note of; we are carrying out a large-scale controlled clinical trial to see whether the drug AZT will prevent patients who have so-called AIDS-related complex from progressing on to full-blown AIDS.

I should perhaps expand a little on that in view of the earlier questioning. When a person is first infected, there may be a period during which the individual has no symptoms. There is then, in many patients, a period of time characterized by the term "AIDS-related complex," during which some symptoms occur, such as swelling of the lymph nodes, but not one of the terribly serious or lethal complications; and the trial that we are conducting identifies patients during this phase of the disease, and we are using the drug AZT to see whether it will prevent progress of the disease from AIDS-related complex to full-blown AIDS. This trial, in fact, is supported by research funds made available from the Department of Defense.

My concluding comment would be that, as we look forward to the future, I think it is very hard to predict or project with accuracy the health or social consequences of this disease; but our commitment in the Veterans' Administration is to ensure that we do not overlook any opportunity to contribute to bringing this terrible scourge under control.

At this moment, we are taking steps to strengthen the organization of the Veterans' Administration to ensure that we can better plan our patient care activities, our research, and our educational contributions. And we very much appreciate the interest and support of this committee as we continue with this work. Mr. Chairman, that is a brief opening statement, but we will be pleased to respond to questions.

Chairman CRANSTON. Thank you very much, Dr. Gronvall. Dr. Clinton.

[The prepared statement of Dr. Gronvall appears on p. 81.]

STATEMENT OF DR. J. JARRETT CLINTON, DEPUTY ASSISTANT SECRETARY OF DEFENSE (PROFESSIONAL AFFAIRS AND QUALITY ASSURANCE), OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS, ACCOMPANIED BY COL. WILLIAM BANCROFT, MEDICAL CORPS, U.S. ARMY

Dr. CLINTON. Thank you, Mr. Chairman. We are very pleased to be a part ot this hearing and have an opportunity to tell you and the public about the programs and policies of the Department of Defense. We have already prepared for you a written statement that describes much of our data and information, the programs and the policies. I assume that will be a part of the record. We request that it be so.

Chairman CRANSTON. Yes, it will be.

Dr. CLINTON. What I would like to highlight at this time is the distinguishing characteristics of our actions which are to focus predominantly on the infection with HIV virus, the human immunodeficiency virus. The AIDS cases, while real and substantial in the military, do not make an enormous burden on our medical care system at this time. I think the distinguishing characteristic of the Department of Defense actions began almost 2 years ago, to identify those individuals who have the infection and the infection alone, and find ways to prevent their progression to more serious complications of that infection, to prevent the spread of the infection in our own community and the public at large.

Now, about 2 years ago, the first action was taken to test all civilian applicants to the military. Now, we have tested nearly a million people who have applied to the military and have a constant rate of approximately 1.5 positives per 1,000.

Chairman CRANSTON. Is that when somebody applies to become a member of the military?

Dr. CLINTON. That is correct.

Chairman CRANSTON. All such people are tested?

Dr. CLINTON. Every one, whether it be for Officers Candidate School or whatever category it might be. They are all tested.

Senator MURKOWSKI. Does that include the National Guard?

Dr. CLINTON. Yes. 1.5 per 1,000, and strikingly, that rate has stayed approximately the same. There are no significant statistical changes of any consequence over an 18-month period.

Chairman CRANSTON. What is the rate again?

Dr. CLINTON. 1.5 per 1,000. That would be 3 people in 2,000. There is a good deal of variation in those rates as you look to those applicants who come from New York City and in parts of California, as opposed to the Midwest; but nonetheless, that is the average rate.

Now, not long after that, we established a policy of testing all those in the Active Force; and we have nearly completed that. The rate there is very similar. More precisely, it is 1.6 per 1,000. Now, we have an Active Duty Force of slightly over 2 million people. We have identified approximately 3,000 individuals, in round numbers, who are infected with this virus.

More than half of them have no other pathology, no other symptomatology of a disease. The other half have, in varying degrees, pathology with about 4 percent of those having the definition of disease AIDS. You can see that the majority of the people that we are dealing with now are early in the infection. As has been noted earlier, we are not sure to what extent these people will progress to either ARC or AIDS.

That, we think, is providing very useful information to the Centers for Disease Control. We have provided for the written record some of the reports on the civilian applicant data that are routinely reported by CDC to the profession and the public at large. And through various professional presentations, we provide data with regard to the demographics of our own testing of the Active Duty Forces.

We believe that by preventing those with the infection from joining the Active Duty Forces and by screening those and curtailing their assignments to the United States and watching them very carefully from a medical standpoint, we will reduce the impact of the infection on our own military force and, in the long run, on the VA's medical efforts.

We hope then that this combination, combined with our information and education program, can indeed make AIDS and the infection with HIV as minimal as might be possible within our community. Thank you, Mr. Chairman.

Chairman **Cranston**. Thank you very much. Dr. Curran.

[The prepared statement of Dr. Clinton appears on p. 91.]

STATEMENT OF DR. JAMES W. CURRAN, DIRECTOR, AIDS PROGRAM, CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL, PUBLIC HEALTH SERVICE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. **Curran**. Thank you, Mr. Chairman. I am very pleased to be here to represent the Centers for Disease Control; and we, too, have provided written testimony for the record.

I would like to make a couple statements in addition to the written testimony. First, cooperation and communication with both the Veterans' Administration medical group and the Department of Defense about the incidence and prevalence of AIDS and reported AIDS cases as well as AIDS antibody testing has been quite helpful to the CDC in terms of providing information that can be of use in understanding the problem in the United States.

Second, since the disease was discovered 6 years ago, there have now been reports of cases in 112 countries throughout the world. It is truly a worldwide health problem, and there is worldwide medical and scientific and public health expertise to draw from to deal with the problem. There may not be enough people working on it, but there are certainly many people with a lot of experience.

As I pointed out, cases are reported from all 50 States, the District of Columbia and Puerto Rico. In most of the cases thus far, over 90 percent have been in homosexual men and heterosexual intravenous drug abusers. I think it is important to note that, in Dr. Gronvall's testimony and in our testimony and that of the Veterans' Administration, about 40 percent of the cases have been in heterosexual men and women who are intravenous drug abusers. And to my knowledge, about 4 percent of the cases in the United States are related to heterosexual contact with men and women who are infected with the virus.

Many people fail to understand that the majority of heterosexual contact and perinatal transmission in the United States thus far has been directly or indirectly related to intravenous drug abuse. Intravenous drug abuse is at the very roots of the heterosexual epidemic in the United States; and of course, controlling heterosexual transmission will be inextricably linked to the control of intravenous drug abuse.

I don't know of any other sexually transmitted disease in heterosexual men and women in a country which has begun with intravenous drug abuse and has been so closely linked to intravenous drug abuse.

There is a great deal that is known about AIDS, and there is also a great deal that is unknown; and I think that we have publicly had a lot of uncertainty about what is known and what is unknown. Some scientists say we are totally perplexed in our search for a vaccine. That we need to understand the immune system more completely; and that there is a struggle to come up with safe, effective therapies. However, there is a great deal known about modes of transmission, and it is important not to mix up what is known about the modes of transmission with the lack of knowledge in some of the more basic scientific areas.

One important question that has been referred to is the outcome among infected people. What will happen to someone who is infected with the AIDS virus? Let me make a couple of comments about that.

Infection with the AIDS virus is probably lifelong—almost certainly lifelong. It is a persistent infection which continues to damage the immune system of the infected host. AIDS, the very serious life-threatening infections and cancers, is the end of that infection process, the end of the spectrum.

People are often asymptomatic for the first few years. And there are now at least 20,000 infected people who are involved in prospective studies to study the outcome in them. Because AIDS has been so recently recognized, virtually none of these 20,000 people have been followed for more than 7 or 8 years. The most extensive study is one in San Francisco, with the San Francisco Health Department and CDC, in which nearly 7,000 homosexual men have been followed, actually retrospectively, since 1978.

In that study, fewer than 1 percent of men infected for 2 years have developed AIDS; but by the end of 7 years, 30 percent have developed AIDS. And in those who have died AIDS has been been the cause in 95 percent of those deaths. So, it is far and away——

Chairman CRANSTON. 95 percent?

Dr. CURRAN. 95 percent of the men in the cohort. Of the 6,700 men, average age 32, over 700 now have developed AIDS. There are many other issues that I will be willing to respond to with questions; I see my time is up. Important questions are incidence of prevalence and infection. CDC is involved in surveillance, epidemiologic studies, and prevention and control. With regard to prevention and control, the efforts are aimed at the general public, school age and school children, infected people and people at highest risk, as well as health-care workers.

The testing and counseling issue primarily involves those people at high risk for infection. One comment I would like to make about testing and counseling is that the objectives of it are to provide counseling to infected people primarily and counseling to people who are at increased risk for infection. Testing without counseling is not likely to be very productive.

Another major objective is for diagnostic purposes. I think Dr. Rowland, in his House testimony, said that telling someone they are infected with the AIDS virus is like telling them they have cancer; and the first thing you want to know is: Doctor, what are you going to do for me? And I think that is the first question that the VA will answer and anybody else will answer.

Chairman CRANSTON. What response are you able to give to that question? Or what answer is a doctor able to give to that question?

Dr. CURRAN. I think a doctor has to be very knowledgeable about the current state of the art in terms of therapy and outcome. What I would tell a patient is that, among homosexual men, most people remain without symptoms for 2 years. Thirty percent of people will develop a life-threatening disease within 7 years; 70 percent won't.

I would say that there are a lot of studies to try to determine which people will and which people won't, that there are some additional tests of your immune system that we can do to help differentiate your status, and I would like to follow you very closely. If you need more time for discussion psychologically, et cetera, I will provide you with additional help. I would like to say my door is always open. Things like that.

Confidentiality in record keeping are particular problems in hospitals, and there has never been a disease in which confidentiality is more of a problem than AIDS. So, that is something that any hospital has to deal with when they start to do routine testing.

Last, is the training of health-care workers. Since the beginning there has been a concern about the role of health-care workers in caring for people infected with the AIDS virus. This has been intensified with reports of infection in health-care workers that have been occupationally exposed. These occupational exposures are rare, but——

Senator Murkowski. On that point, we have heard so much about the rights of the AIDS victim. What about the rights of the nurse? Are the nurses—those persons who have to give the individual care all the time, as opposed to the doctors who come in and out—demanding that they have advance notice of whether they are likely to be treating AIDS infected patients so that they can take precautions? What about their rights?

Dr. Curran. The issue of precautions for health-care and laboratory workers was addressed in 1982, about 2 years before the AIDS virus was discovered, because of the concern that this was caused by something that was circulating in blood. The precautions that are necessary for health-care workers are really necessary for all health-care workers exposed to blood and body fluids, irrespective of whether they know the antibody status or not because most people infected with the virus are not going to have AIDS.

In an outpatient setting, for example, where there could be no way of knowing the test results ahead of time it is going to be important for all health-care workers to take precautions—wear gloves. If they are involved in a procedure where body fluids might be splattered they should wear goggles and masks. It is important that they take these precautions irrespective of the question of whether they know the antibody status of the patients.

We think it is an open question of whether knowledge of antibody status increases precautions that health-care workers take. In one way, you could argue that it would. It may also diminish the care for the patient if they were to be avoided or isolated, in terms of their medical care.

I think that is a very important question to answer, and undoubtedly there will be more demands for testing for that reason.

Chairman Cranston. We are going to hear from a representative of the American Nurses' Association this morning. Does that complete your statement?

Dr. Curran. Sir, that completes my time. [Laughter.]

Chairman Cranston. If there is anything else you have an urgent need to communicate, don't hesitate. Otherwise, we will start asking questions.

[The prepared statement of Dr. Curran appears on p. 117.]

Chairman CRANSTON. John, I would like to ask you first if you have any comments on this New York Times story that appeared today on page 1, indicating that you oppose mandatory testing of VA hospital patients.

Dr. GRONVALL. I have read the story, of course, Mr. Chairman; and the story accurately states that I was interviewed yesterday by the reporter, who asked questions about the position of the Veterans' Administration. When I discussed it with him, I indicated that we had made recommendations to the White House work group which, in turn, would be the subject of deliberation at the Domestic Policy Council and that, since that recommendation is a confidential recommendation from the Veterans' Administration, I couldn't really discuss what was included in that recommendation.

Chairman CRANSTON. Is the story in the New York Times accurate?

Dr. GRONVALL. I have read it with great interest, but——[Laughter.]

But not from the standpoint of detailed analysis to compare the story with VA documents; but I believe the story, on first reading, appears to be accurate.

Chairman CRANSTON. Thank you very much.

Senator MURKOWSKI. A good answer.

Chairman CRANSTON. Yes. Could you make a copy of the memo referred to and quoted available for the committee?

Dr. GRONVALL. Mr. Chairman, my understanding of that, is that, of course, the document that we provided to the White House was a confidential recommendation from the Veterans' Administration; but with that understanding, if it is requested by the committee as a part of your oversight role, we can make the document available to you, with that understanding that it is a confidential document.

Chairman CRANSTON. I do so request on behalf of the committee.

Dr. GRONVALL. Thank you. We will supply it.

Chairman CRANSTON. Thank you very much.

[Subsequently, the Veterans' Administration furnished the following information:]

The paper on AIDS testing was provided to the committee by letter and dated July 2, 1987.

Chairman CRANSTON. What specific guidance has the VA provided to its field facilities with regard to testing for the HIV antibody?

Dr. GRONVALL. I will ask Dr. Cohn to describe that. We have been very concerned, and we have issued a great deal of very specific guidance to our field facilities. Dr. Cohn?

Chairman CRANSTON. All right. Dr. Cohn, if you would reply very briefly now and give us more for the record?

Dr. COHN. We have issued 17 circulars, Senator, and we have three additional ones in draft, doing a life history of our involvement with the AIDS epidemic. A number of those circulars deal with the issue of testing. The two cardinal areas that we have given guidance have to do with, first of all, Project Lookback, or Program Lookback, which as you know is related to the blood transfusion issue; and the other area is the use of the AIDS antibody test as a clinical guide to aid the physician in making a diagnosis.

So, essentially, the guidance is in those two general categories. We have also had opportunities to discuss with individual facilities the desirability of providing voluntary testing for special groups at risk, namely patients who are in our drug abuse units.

Chairman CRANSTON. What have you told the local people about informed consent and counseling?

Dr. COHN. Very well. As far as informed consent, that categorically must be obtained; and that is part and parcel of AIDS antibody testing. That informed consent should take the form of an exchange of information with the patient about the disease, the purpose of the test; that obviously the results of the test will be discussed with the patient.

And the second part of your question, sir?

Chairman CRANSTON. Is that noted in the medical record?

Dr. COHN. That should be noted in the record. Yes, sir.

Chairman CRANSTON. Is counseling also provided?

Dr. COHN. Counseling also is a part of the testing, and that should be provided both pre- and post-test and is.

Chairman CRANSTON. Thank you.

Dr. GRONVALL. Mr. Chairman, I might just add a sentence. We have been concerned to ensure that that policy on informed consent is uniformly followed up and carried out. So, as recently in fact as last week in a conference call to all of our medical centers, we reminded our medical center personnel of the need to have informed consent in every case, to have that documented in the record, and to ensure that counseling before testing and after testing was done in every instance.

Chairman CRANSTON. Thank you. John, could you give us your personal and professional views of the proposal to test all inpatients in VA Medical Centers? What I would like to ask you to do is to comment specifically on each of the following, if you can: The need or lack of need for such testing; the need or lack of need for pre- and post-test counseling; the need or lack of need for informed consent; the cost of the proposal; and your ability to guarantee the confidentiality of test results.

Dr. GRONVALL. Yes, sir, I would be pleased to comment. In fact, I am unaware of a proposal by anyone that we establish as a mandatory process testing of every veteran who comes to us for care. The President, in his public statement, called for a review of the issue of testing in the VA; and that review has been under way, and it led to the preparation of the document that we were discussing earlier.

Chairman CRANSTON. Such a proposal may well come from some authoritative place, so I would like to get your professional and personal views of that approach.

Dr. GRONVALL. I think our view has evolved in consultation with the CDC and Public Health officials. And our view is that testing should be focused on those groups of veterans where there is reasonable likelihood of a payoff by testing and that the requirement for counseling before and after testing is an absolute imperative. It is our stated policy that all testing should be done with informed consent. We have uniformly felt very strongly that the patient needs to be aware that the test is being performed and why it is being performed, since our desire is to have the patient cooperate with his or her physician in changing behavior or doing whatever is necessary, both in the patient's best interest and in the best interest of contacts with the patient.

So, we have continued to insist on counseling and informed consent. In regard to confidentiality, we view the results of the test as a confidential part of the medical record, entered into the patient's medical record, but that that confidentiality exists with regard to this medical information in the same way that it does with any other diagnostic information.

Within the hospital, the staff immediately responsible for care of the patient, of course, need to know what the patient's medical condition is; but, as has been commented earlier, all of the workers in a hospital need to conduct themselves and take care of patients and take care of the facility in such a way that they are protected from the risk of infection. That includes hepatitis and other infectious diseases, of course, as well as AIDS.

So, we have educated our entire staff through extensive training programs to ensure that they conduct themselves in a safe fashion.

Chairman CRANSTON. What would you estimate the cost of such a program to be?

Dr. GRONVALL. The cost estimates, based on our current experience, are that the preliminary screening test for AIDS is costing us about $5 per test, and then the corroborative test costs about $17. If we have a positive result or a questionable result and require so-called tertiary testing, which is a more elaborate series of tests, that can run up to approximately $100 per specimen.

Chairman CRANSTON. If you were going to have a program of testing everybody who came into the VA and also had to give pre- and post-test counseling—go through all the procedures—what would the total cost be?

Dr. GRONVALL. I don't have a figure that I could give for that.

Chairman CRANSTON. Could you furnish it for the record?

Dr. GRONVALL. Yes.

[Subsequently, the Veterans' Administration furnished the following information:]

> Since a testing program of this magnitude has not been undertaken before, it is difficult to estimate exactly how much it would cost. Our best estimate for a testing program that involves a "screening" ELISA with confirmatory Western Blots and pre- and post-test counseling is $24,855,000 per year. This does not include followup examinations and care for those veterans identified as HIV positive.

Dr. GRONVALL. During any individual year, we have medical contact with about 3.5 million veterans. A testing program that was expanded to that extent could reduce the per-test cost. Our estimates, based on experience, are that the counseling part of the testing program is in fact more expensive than the laboratory component and is, as I said, an extremely important part of the testing.

Chairman CRANSTON. I guess the number of inpatients would be 1.4 million. Right?

Dr. GRONVALL. Yes. We hospitalize about 1.4 million veterans per year.

Chairman CRANSTON. If it was decided that the VA should implement mandatory AIDS testing programs, do you believe it would have the statutory authority to condition eligibility for VA hospital care—which for 95 percent of your patients is an entitlement—on the testing being performed on them?

Dr. GRONVALL. That, of course, is a legal question; and I would like to ask Mr. Ibson to comment.

Chairman CRANSTON. Fine.

Dr. GRONVALL. My understanding is that at present we would not have such authority. Mr. Ibson?

Chairman CRANSTON. Mr. Ibson?

Mr. IBSON. Thank you, Mr. Chairman. I would have to say that we have not undertaken a definitive legal analysis of that question.

Chairman CRANSTON. Let me ask a follow-up question of you. Does the VA believe it has the statutory authority to conduct the test on a patient's blood without that patient's informed consent, or at least without offering the patient a right to refuse?

Mr. IBSON. My preliminary view would be that informed consent is a prerequisite, sir.

Chairman CRANSTON. If you would give a detailed answer in writing to both questions, the preceding one and that one, I would appreciate it.

Mr. IBSON. We will be pleased to do so. Thank you.

Chairman CRANSTON. Thank you.

[Subsequently, the Veterans' Administration furnished the information which appears on p. 132.]

Chairman CRANSTON. Given that many VA Medical Centers are expanding their voluntary testing programs, does your Lexington Laboratory presently have the capacity to meet these growing demands?

Dr. GRONVALL. We are equipped now to do very sophisticated testing, not only at Lexington, but at a number of our other facilities. We have expanded our capability of testing so that we can do the full range of testing not only at Lexington, but at New York, Albuquerque, San Francisco, Denver, and New Orleans. And we are continuously reviewing our laboratory capability to expand that capacity.

Chairman CRANSTON. Could you presently process all VA tests if all inpatients were screened?

Dr. GRONVALL. If a decision were made to screen all VA inpatients, it would require some time to gear up the laboratory capability to do that.

Chairman CRANSTON. What plans, if any, do you have to establish such labs at other VA Medical Centers?

Dr. GRONVALL. Dr. Cohn might comment on that.

Dr. COHN. None other than as Dr. Gronvall read, sir. I would just want to add that I think our Lexington reference lab is reaching the point of being overloaded at the present time with a modest testing program that I addressed in your earlier question. So, clearly, there would have to be the establishment of other labs or contracting out to do the entire population.

Chairman CRANSTON. Would you compare the costs of analyzing the test in-house and by contract?

Dr. GRONVALL. At the present time, our in-house experience is that it is cheaper than having it done on a fee basis. Our full statement has some example figures. I mention that a screening test costs us about $5 per test. Our private sector fee basis experience is that that same test runs from $12 to $30. We have additional data that we could supply on the more elaborate testing in regard to our cost versus the contract cost.

Chairman **Cranston**. If you had a large expansion of the testing, would you have to go to contract?

Dr. **Gronvall**. It would depend, I think, on the timetable and availability of funds as to whether we could expand VA laboratories sufficient to meet that program.

Chairman **Cranston**. Thank you. Frank, my time is up.

Senator **Murkowski**. Thank you very much, Mr. Chairman. From the questions that you were posing and those that I have and the other members have, it will be somewhat representative of the general process here and the extent of concern and probably show the basic ignorance that exists on the issue. I would like to go back to this figure that I used and that Dr. Curran qualified, the qualification being males in the age group of 20 to 50 and that being a correct interpretation. If indeed 1 of 30 have been infected in the age group of 20 to 50 males, provide the number that you are using, Doctor, in the sense of how many individual males are infected and how many of those are aware of it?

Dr. **Curran**. My estimate is coming full circle in the sense that it began with an estimate of how many people were infected, that is 1.5 million.

Senator **Murkowski**. 1.5 million?

Dr. **Curran**. 1.5 million total. And in the 20 to 50 age group in men, over 90 percent would be men.

Senator **Murkowski**. Yes.

Dr. **Curran**. And in the 20 to 50 age group, about 90 percent of those men would be included. So, over a million would be in that group, if 1.5 million people are infected.

Senator **Murkowski**. Right. Now, out of that million, how many are knowledgeable that they have the infection?

Dr. **Curran**. We have those people who have been diagnosed with AIDS who are living; that is about 15,000, plus another 7,000 to 8,000 yet to be reported. We have people who have been tested through blood bank screening programs and through the Department of Defense, the Foreign Service, Job Corps, and other programs, where testing is done. We have people who have gone to federally supported testing and counseling sites, and there are estimated to be 50,000 who have been tested and counseled through the CDC supported sites.

All of this comes out to a reported estimate, I guess, of approximately 10 percent.

Senator **Murkowski**. Ten percent?

Dr. **Curran**. Approximately.

Senator **Murkowski**. Of the million?

Dr. **Curran**. Approximately.

Senator **Murkowski**. About 10 percent know it; the rest don't.

Dr. **Curran**. It is likely that there are additional people who have AIDS related illnesses who have gone to private physicians, who have been tested and the results haven't been reported, for example. So, we don't know about those.

Senator **Murkowski**. Either they know they are infected or they don't.

Dr. **Curran**. The bottom line answer is that well more than half of those persons infected—whatever the number of infected is—probably are not personally aware or have not been personally counseled.

Senator **Murkowski**. All right. In your professional opinion, do you feel that there is justification that those that don't know that they have been infected know it? Is society going to be better off?

Dr. **Curran**. I think it is quite important for people to have counseling and testing and for people who are infected to know it because I think they can make more informed choices.

Senator **Murkowski**. Then, if you don't have some kind of a mandatory blood testing, how are those people going to know it?

Dr. **Curran**. I think there is no question that increased testing and counseling—increased coverage particularly of those populations likely to be infected—is a major objective and a major goal. What are the barriers to getting that done?

One of the barriers is increased resource availability, not just money, but also people to do the counseling and testing. I note that, of the patients reported at the VA hospitals, over 50 percent are Black and Hispanic. In the United States, about 40 percent of patients are Black and Hispanic. Many people, especially in minority populations, may not have a doctor. They don't have anybody to go to.

I think it would be very important to turn the 1.5 million people over to concerned physicians and concerned counselors. I would love to have that happen.

Senator **Murkowski**. Sure, but those people don't know if they are infected, and you don't know who they are.

Dr. **Curran**. The other thing to point out, I think, is that there are lines at testing and counseling centers around the country. I am told in California you wait 4 weeks to get tested in some centers. So, there needs to be a lot more testing.

Senator **Murkowski**. How are we going to get there from here if there isn't some kind of mandatory testing because these people aren't necessarily going to go and say I want a test for AIDS. Something may motivate them; they might recall an experience, and they may decide that they want to make that decision for themselves. But you are not going to pick up a very large percentage of this infected group that is out there that doesn't know that they are infected unless there is some method to do it.

Just as an example, we had here—after Senator Zorinsky's unfortunate passing—a cholesterol test offered in this building. Now, it was almost an instantaneous operation. You went down and you got a little quick prick in the thumb, and you were advised what your cholesterol count was. Is there a methodology associated with blood testing that can be done in a very expeditious manner where something like that would offer an individual a voluntary option to ask that his blood be examined for AIDS as well?

Dr. **Curran**. There are 1,200 federally supported testing and counseling centers throughout the United States, and many of those centers are State controlled and federally supported. In many of those centers, tests can be done anonymously, and people can pick up their results anonymously. I think that that is a valuable thing, but the concern I have about it is that, if you have a very elevated cholesterol, that is nice to know; but what are you going to do about it? You have to go to a cardiologist or somebody who can tell you just exactly what that means for your own personal life.

I think that is the same thing with the AIDS test. I personally believe that everybody who is infected with the virus, and everybody who is at any increased risk, needs to know a lot more, and they need to know if they are infected.

Senator MURKOWSKI. Yes, but you are leaving me hanging, Doctor, because how am I going to get that done?

Dr. CURRAN. I think we need to make it a standard of medical practice, for one thing.

Senator MURKOWSKI. You are implying, then, a mandatory screening of some kind, without saying so.

Dr. CURRAN. I don't think I am implying mandatory. I like the word "routine" pretty well.

Senator MURKOWSKI. All right. I will buy that. [Laughter.]

But how do you motivate people to be tested? A few minutes ago, you said in the blood testing program, you have some tests for AIDS; but does somebody have to sign, or do you anonymously test? You see, there is no definitive anthology here.

Dr. CURRAN. It might be useful to discuss the word "mandatory" from the point of view of what it means to the person on the other end of the needle. If an elevated cholesterol meant that you couldn't be in the Senate any more—and I am serious—that would be a problem—and the mandatory testing programs have been in blood banks and in recruits to the military. And the result of the word "mandatory" from the point of view of those who are going to get tested is that people can't donate blood and they can't enter the military if they have a positive test. Now, if the perception of the public is that, on a national testing day, all Americans get tested and something bad will happen as a result of that, in addition to finding out that they have a deadly disease, there is going to be a lot of public resistance, even among people who aren't at risk. So, the word "mandatory" is an extremely loaded word on both sides.

I mean, virtually no test is mandatory on hospital admission. Many are routine.

Senator MURKOWSKI. All right. Let's take your word "routine." Do you mean in the process, which becomes routine, of taking blood samples that there be an AIDS test given as well?

Dr. CURRAN. I think in that 20 to 50 year age group and in many hospitals and health care settings AIDS testing ought to be at the top of every doctor's thoughts, in which case they shouldn't just wait to question people about their risk. They ought to be routinely offering the test to every patient in that age group.

Senator MURKOWSKI. Where does this conflict with the headline in The New York Times that says "Mandatory Tests for AIDS Opposed by Doctors"? Would you accept that if it said "routine AIDS tests"? You tell me how to get there from here, gentlemen. Am I expressing a dilemma that I am not sharing with you? Dr. Gronvall, maybe you can help enlighten us on this. You heard Dr. Curran's statement that the routine aspect of it would give you a window into those million-plus that are out there that don't know.

The VA tells us that mandatory AIDS testing is opposed by doctors at the VA. How do you bring "routine" into "mandatory" to make it acceptable, if indeed it is?

Dr. GRONVALL. I don't know that the two terms can be harmonized.

Senator MURKOWSKI. Address the objective then because that is really what we are all trying to develop—a process that is workable, that is supportable, that addresses the rights of the individual and their privacy, and yet benefits the public health.

Dr. GRONVALL. Yes. In my view, it is a highly laudible goal that, in the health-care system, every individual who comes to a physician, a clinic, or a hospital and falls into either an age group or a category of symptomatology or a characteristic of lifestyle or other disease, that means that that person is at some significant risk of being infected with the AIDS virus, that that person be routinely counseled by his or her physician that testing for the infection of the AIDS virus is highly desirable. What that would mean and what the individual could do about it, if it turns out that the individual is in fact infected, in that context I believe a major expansion of routine testing targetted on certain categories of individuals coming for health care is desirable.

Senator MURKOWSKI. How do you motivate that group of individuals in the age group of 20 to 50? Public pronouncements that they are a high-risk group?

Dr. GRONVALL. The context, of course, of my comment is that the individual has come to a physician or a clinic for some reason. I am not making a comment on a population-wide epidemiologic survey. I think that is quite a different matter.

My comments are restricted really as the responsible person for a health-care system. My comments are restricted to those individuals who, for some reason, come to us seeking care or come with a concern. I believe many individuals are coming to doctors and clinics because they are concerned about the possibility they might be infected with AIDS, and they are asymptomatic; and we are seeing increasing numbers of such people come.

Senator MURKOWSKI. I accept that, but by the same token, Dr. Curran referenced that there are a million people out there, and 90 percent of that age group of 20 to 50 probably are not necessarily aware of their infection. We are assuming that they are going to be motivated simply because they are in that age group, to come in and voluntarily make a determination. I guess time will tell whether that is enough.

Dr. GRONVALL. Yes.

Senator MURKOWSKI. We will have to see if we can initiate a process that is workable or whether there will have to be some exterior force to motivate this group. That is what I am concerned about. I think you are giving us a very qualified answer, and I appreciate that; but by the same token, we have a responsibility of initiating a reaction that is representative of the people. I don't know that that qualification, as broad as you have presented it, is really going to get us there in a time frame that equalizes the tremendous spread and advancement of this disease in the last 6 or 7 years. That is what I am concerned about. I guess I have one last question, Mr. Chairman.

What do you think the Congress or the Senate of the United States should be doing, other than holding hearings and talking about it? The No. 1 thing that should be done that is not being done is what?

Dr. GRONVALL. That is a very important question, I think, but an extraordinarily difficult one to capture the complexity of this epidemic into one overriding objective. I think that the Congress should do everything it can to ensure that there is accurate information available for portrayal to the public, do everything it can to best ensure that the many activities throughout the country in terms of patient care and research and education are coordinated in some sense, even if it is only through the availability of information about what is going on.

And I think by these kinds of hearings and others, stimulate the development or existence of perhaps a more coherent set of activities—research, education, and patient care throughout the country. I think to confront this disease is going to require the best efforts of every sector of a highly pluralistic health system and social system in this country. I am not an advocate of a national plan in the sense of the creation of a czar—a single individual or a single ironclad plan—that mandates everything that should be done because I think that sort of approach misses the genius of the pluralism and dynamism of America; but I believe presenting the information to the public and working to ensure that our efforts are known across the range of the health system and are coordinated and then providing the resources to capitalize on every possible opportunity as it presents itself to improve our education and our research and patient care activities is the objective.

Senator MURKOWSKI. Thank you, Mr. Chairman. I have some other questions, which I will ask Mr. Principi to submit for the record.

Chairman CRANSTON. Thank you very much, Frank.

I presume part of your answer would be that Congress should pay particular attention to health professionals in seeking advice as to what we can do?

Dr. GRONVALL. Yes, sir. I think expert medical and scientific advice is a key component of dealing with a disease whose solution ultimately will come out of research and understanding of the characteristic of the virus and its mode of action.

Chairman CRANSTON. Bob?

Senator STAFFORD. Thank you, Mr. Chairman. Gentlemen, the Chairman and the Ranking Member of the committee have asked most of the questions that might have occurred to me. And indeed, they have asked several that did not; but one has occurred to me that I would like to direct, to Dr. Curran.

We have listened to a considerable discussion of the incidence of the disease, the prospects for handling those who have or may have the disease, or preventing its spread. But nobody has said anything about the possibilities of better treatment for the disease than we have had up until now. I wonder, Doctor, if you could comment on where we are in trying to find something that will not only stop but cure this terrible disease?

Dr. CURRAN. Doctors Gronvall and Clinton may want to add something to this. In my written testimony is a discussion of the clinical trials that are being supported by the National Institutes of Health. There is approximately $100 million in the Public Health Service budget for therapy studies.

Currently, there is one drug that is licensed for the therapy of people who are infected with the AIDS virus, and at this time use of that drug is restricted to people who have been diagnosed as having AIDS. Some additional studies being conducted at the VA, at Walter Reed, and other places may extend the use of that drug. The drug, azidothymidine, is a drug that is very expensive and has considerable toxicity but does prolong life and improve the well-being of people in this select category of patients.

There are many other drugs. This drug and other drugs being tested do not eradicate the virus. They do not cure the person, but merely hold it in check to prevent it from reproducing as quickly. So, there is not yet any sort of magic bullet. There is a lot of effort in this area; and there is one drug licensed.

Dr. GRONVALL. I think it would be helpful for Dr. Cohn to comment.

Chairman CRANSTON. I would appreciate that.

Dr. COHN. There are three broad approaches to the treatment and, hopefully, the ultimate cure of AIDS. One is the antiviral approach. Dr. Curran has alluded to the one drug that is available in the marketplace.

Second, so-called immune modulators; and third, vaccine. You have probably heard and read a fair amount about vaccine effort. Most experts predict that we are probably 3 to 5 years away, at least, from having an effective vaccine, maybe longer. The point I would like to make is that there is a tremendous amount of activity in all of these arenas.

There is a tremendous flurry of activity among researchers. I think the Third International Conference on AIDS, which was held in Washington, is but one rather graphic example. One could hardly move about in the hallways and corridors at the hotel where it was held because there were so many, many people—literally thousands of people.

There have been tremendous contributions in our system, of course, at NIH and elsewhere in terms of delineation of the virus and assorted other work. It would appear that the best and ultimate approach would probably be a combination of these different modalities, that one treatment alone will probably not do the job as you are asking, that it will be a combination approach that will be the ultimate solution to the disease.

Senator STAFFORD. Thank you, Dr. Cohn. Thank you, Mr. Chairman.

Chairman CRANSTON. Thank you very much, Bob. I would like to ask Mr. Ibson regarding the legal opinions that I requested, could you please give us those by July 6?

Mr. IBSON. We will make every effort to do so, Senator.

Chairman CRANSTON. Thank you. Colonel Bancroft, I would like to address some questions to you. What does it cost the Army to perform each test at the present?

Colonel BANCROFT. The tests that we do are done by contract laboratories. We estimate that they are approximately $5 a person at the present time.

Chairman CRANSTON. Could you give us a list of those laboratories for the record?

Colonel BANCROFT. Yes, I certainly can.

Chairman CRANSTON. I think the VA estimated it would cost substantially more than that.

Colonel BANCROFT. We have been able to contract at a lower price because of the large volume.

Chairman CRANSTON. That doesn't include any cost of counseling, does it?

Colonel BANCROFT. No, sir.

Chairman CRANSTON. What are counseling costs per test? Or do you know?

Colonel BANCROFT. The counseling costs I could not estimate. They would be built into the regular costs of medical care.

Chairman CRANSTON. Are the Army's costs typical of the costs of other services?

Colonel BANCROFT. Yes.

Chairman CRANSTON. How are the tests processed? For example, does the Army have one centralized laboratory facility for processing the tests? What about the other services?

Colonel BANCROFT. The Army has most of their tests done by the Damon Laboratories, which is a contract laboratory located in Texas, with a subsidiary laboratory in California. Each individual has an initial immunosorbent test done. If that is negative, it is not repeated; and the individual is considered negative. If it is positive, it is repeated.

Chairman CRANSTON. Would you amplify in writing just how the other services proceed?

Colonel BANCROFT. Yes, sir.

[Subsequently, Colonel Bancroft furnished the following information:]

All HIV testing for all Services follow the same procedures: each individual has an FDA approved enzyme linked immunoassay serologic test and, if positive, an immunoelectrophoresis test (Western Blot). Special tests are done if the Western blot analysis is indeterminate.

The contract costs are as follows:

U.S. Army

All HIV testing for the civilian applicants and the active duty, reserve and National Guard is done by Damon Laboratories of Needham Hieghts, MA. The cost per person tested is:

	Total people	ELISA + Western Blot
Civilian Applicants	747,000	$4.10
Active Duty Army	456,624	$3.99
Reservists	277,000	$9.29 (+ blood drawing)
National Guard	290,763	$9.55 (+ blood drawing)
Special purpose individual tests:		
Western Blot		$13.77/test
Recombinant ELISA		$ 6.33/test

U.S. Navy/Marine Corps

ELISA tests are done by Electronucleonics Inc., Bethesda, MD and Western Blots by Biotech Research Lab, Rockville, MD.

Active Duty and Reserves:		
ELISA	800,000	$ 0.62/test
Western Blot		$30.00/test

U.S. Air Force

All tests are contracted to Blood Systems Inc., Scottsdale, AZ.

Active Duty, Reserves and National Guard:		
ELISA	404,000	$ 3.51/test
Western Blot		$14.13/test
Special Purpose Tests:		
Recombinant ELISA		$11.91/test
Indirect Fluorescent Antibody		$ 9.37/test

Chairman **Cranston**. Thank you very much. John, back to you. One scientific article has reported that when the antibody test is applied to a low-risk population, the false positive rate is very high, that is, for every 28 HIV positive individuals that the test would correctly identify, the test would also incorrectly identify as being HIV positive 11 individuals who turn out really not to be. What false positive rate have you found?

Dr. **Gronvall**. I would like to ask Dr. Cohn to supply that answer.

Dr. **Cohn**. Our overall experience is roughly along the same lines, Senator. Let me explain this way. The reason for the higher rate of false positives in a low prevalence population is because those individuals are not AIDS antibody positive. They have a low level of other kinds of antibodies that all of us have. These antibodies are so-called cross reacting antibodies, and they actually will react with the test materials, often in an equivocal way; but that equivocal response may be replicated and lead to a final conclusion by the laboratory technician as a positive, when indeed it would be a false positive.

And of course, the implications would be devastating to the patient; that is one of our particular concerns about mandatory or wide-scale testing particulary among such low prevalence populations.

Chairman **Cranston**. Then, even with first-class lab chemicals and equipment and expertise in performing the test, there will still be a large number of false positives, particularly in a population of individuals like VA hospital patients who are ill and are on a number of medications. Is that correct?

Dr. **Cohn**. Generally, that is correct, particularly among patients who are ill; I think that is the key word in your question. Patients with cancer, for example; patients with autoimmune disease.

Chairman **Cranston**. Or people that come to hospitals?

Dr. **Cohn**. People that come to hospitals.

Chairman **Cranston**. Who are often ill.

Dr. **Cohn**. This is often true. [Laughter.]

But not universally.

Chairman **Cranston**. I would like to ask about one seeming discrepancy, for which there may be a rather simple explanation; this 1 in 30 figure that Senator Murkowski was asking about is in sharp contrast to the figure of those who apply to join the military and it seems like it was more like 1.5 in 1,000 or something like that there. Is that because people who may well be infected know they are going to be tested don't come? Or is it because people in the groups that are particularly susceptible don't come? Or how do you explain the difference between those two figures?

Dr. **Curran**. The 1 in 30 estimate came from another estimate, which was the estimate of the number of infected Americans being 1.5 million. If you take the age and sex adjusted military recruit data and extrapolate that to the U.S. population, you come out with something like 270,000 infected Americans. So, there is a sixfold age and sex adjusted discrepancy. I believe the major part of the discrepancy is that homosexual men and current intravenous drug abusers are strongly discouraged from entering the military and don't go to testing stations. That is probably the major discrepancy and there probably are other discrepancies as well. The military data has got to be a tremendous underestimate of the number of infected Americans.

Chairman **Cranston**. Do you have any comment on that?

Dr. **Clinton**. No. The only thing I would add is that the average age of the military recruit applicant is, of course, much younger and would probably be below the 20 to 50 age group, right at 19 or so.

Chairman **Cranston**. Yes.

Dr. **Clinton**. So, it does not reflect the age distribution of America; that may be part of it. How much of that affects it, no one knows at this point.

Chairman **Cranston**. Colonel Bancroft, what false positive rate have you found in screening military recruits?

Colonel **Bancroft**. We find the false positive rate is less than—certainly less than—2 percent and usually less than 1 percent. Using the quality assurance standards that we have set up for the performance of the contract laboratories with rigid quality assurance standards and set criteria for positive interpretation, the performance of the test, and the submission of coded panels to the laboratories, so that the tests are done on a consistent basis from month to month, we find that the false positive rates are very low. Again, our testing system is based on the premise that we do not want to have false positives. And if we do call an individual positive, since it does affect his employment, we want to be absolutely sure we can back that up.

Chairman **Cranston**. I presume that the group you are working with would be in a healthier state than those that show up via hospitals; that would be one explanation. If you can provide us with data, both of you, on this, we would appreciate it.

[Subsequently, the following information was furnished:]

There are no data nor information regarding the state of health of recruit applicants and tested active duty members compared with individuals seeking health-care services in military treatment facilities.

Chairman **Cranston**. Dr. Curran?

Dr. **Curran**. I would like to make a statement on the false positive issue. I think that it is important to recognize that there are at least two tests done. The first is the ELISA test, which is then confirmed by doing a Western blot test or some other procedure. When those tests are done by competent laboratories, I think the military, the Red Cross, and other groups that have been screening low prevalence populations have shown that there are relatively few errors when those tests are done in the appropriate sequence.

Another important point, though, is that it is extremely important to do both tests when there is a positive result because in a low prevalence population the first test may provide misleading results. I think the military and the Red Cross would both say that, before you notify the patient, it is necessary to do both tests. That takes additional time, and it is not something that would be done within the first few hours of hospital admission, but would probably take a few days.

Dr. **Gronvall.** If I may, Mr. Chairman, just add one final sentence to that perspective? In regard to testing blood that is collected for a blood bank, of course, the intent of testing is quite different and the action in a sense is simple. If there is a test which is positive or questionably positive, you can discard the unit of blood and not use it for transfusion. So, the intent of testing when you are protecting the safety of the blood supply is one thing. Now, it is a quite different matter when you are dealing with individual patients being tested to see whether they are infected and whether you need to counsel them as to their own risk of a deadly disease.

Chairman **Cranston.** Given the seriousness, John, of a positive test result and the stigma associated with that result, in your personal opinion does not the potential for harm in testing low incidence populations outweigh the small potential benefit?

Dr. **Gronvall.** That calls for a judgment, and I would find it hard to weigh exactly in any kind of quantitative way. It is clear that a false positive result has a devastating impact on the individual. And as I had said earlier, I believe testing should be done with individuals who are at some risk and should be done under the best of circumstances with appropriate counseling and elaborate efforts to ensure that we absolutely minimize false positives and that we engage the patient's cooperation in what is going on so that we have the best opportunity to work with the patient, to encourage him or her to change whatever is possible to be changed so that we get the best total outcome for the patient's well-being and the well-being of contacts.

Chairman **Cranston.** Dr. Curran, do you have any comment on that issue?

Dr. **Curran.** I think we have had a similar situation with syphilis testing, where the false positive rate for the VDRL, or the common screening test for syphilis, is actually substantially higher than it is for the HIV antibody test. Then, another test is done afterward. I myself have had a false positive syphilis test, and I didn't find that particularly alarming. I think the Red Cross has screened 20 million blood donors and has notified those people who have a positive confirmatory test, and I have not even heard—and I would expect it would be in the newspapers—of people who were having problems in that regard.

I think the military has notified a lot of people, too. So, I think it is a "handleable" problem in terms of a false positivity rate. In my opinion, that is not the major issue.

The major issue is: What do you do with a positive—a real positive? And what are you going to do for that person?

Chairman CRANSTON. I recently learned, John, that at one VA substance abuse clinic, 30 percent of the patients on the methadone program are positive for the HIV antibody. Do you have any data overall regarding the percentages of patients at other VA substance abuse clinics who have AIDS or have tested positive?

Dr. GRONVALL. Dr. Cohn or Dr. Mather, could you help me? I am not aware myself.

Dr. COHN. No other statistics, sir, but that would fall totally within keeping of tests that have been done in the private sector as well as the public sector of patients attending methadone maintenance clinics. For example, in Newark and Jersey City, the positivity rate—the seropositivity rate—is as high as 70 percent in some of those centers.

So, that 30 percent would be totally in keeping with such centers.

Chairman CRANSTON. It seems to me that substance abuse centers are ideal settings for the VA to provide education and outreach for a large number of individuals who are obviously at high risk for AIDS. What kind of education, counseling, and testing are you offering presently to individuals seeking treatment at those centers to encourage them to be tested?

Dr. COHN. In response to your question today, and indeed you brought up the same point, I believe, at the May 21 hearing, we have addressed the question to the 10 leading facilities that are identified in Dr. Gronvall's opening statement. And we are planning to have a formal patient health education program addressed to that population covering a wide variety of areas which I won't take the time to enumerate for you now, but can be provided for the record.

Chairman CRANSTON. Will that be aimed at encouraging these people to get tested?

Dr. COHN. That would be part of the aim. Yes, sir.

Chairman CRANSTON. I should think that should be a very significant part.

Dr. COHN. Yes, sir.

Chairman CRANSTON. If you could give us some more detail on how that program is operating for the record, I would appreciate it.

Dr. COHN. Fine.

[Subsequently, the Veterans' Administration furnished the following information:]

The 10 VA medical centers currently with the highest number of AIDS cases reported Patient and Family Education activities in all of the topics listed below. This information is available to inpatients, outpatients, veterans in the community through VA Health Fairs as well as VA staff participating in community activities including community nursing homes, volunteers, families and significant others, recovering drug abuse patients, worried well (exposed to virus and/or HIV positive), and Zidovudine (formerly called AZT) drug Protocol participants.

The Mental Health and Behavioral Sciences Service is preparing a program guide entitled "Mental Health Issues Regarding AIDS." The program guide will draw from onging programs in several VA medical centers and similar programs in NIDA. It will address AIDS patients education as well as staff approaches to AIDS patients.

The Office of Academic Affairs (OAA) is establishing a comprehensive VA-wide AIDS Patient and Family Education Program. By the end of July, OAA will provide a profile of VA medical centers (VAMCs) AIDS Patient and Family Education activities and programs. This assessment will include program components, target audiences, print and non-print materials supporting educational activities, and the name of contact person by VAMC and will provide the information necessary to assist those VAMCs that need help in developing effective patient health education (PHE) program related to the following information:

—HIV screening and/or results.
—Confidentiality and privacy of individual infected with AIDS.
—Cause of AIDS.
—Major avenues of transmission.
—Methods to prevent spread of AIDS.
—Difference in "high risk" and "low risk" activities.
—Difference between infected with HIV virus but asymptomatic, AIDS-Related Complex (ARC), and AIDS.
—Treatment of AIDS.
—AIDS support groups.
—AIDS as public health issue and impact on society.
—Followup and availability of outreach program services such as housing, shopping, transportation, cleaning, cooking, finance, job counseling, emotional support, testing centers for family and significant others, home care, barbers, legal issues, wills, etc.
—Look Back Program related to blood transfusion.
—Principles of infection control; skills in home care for care giver.
—Clinical Drug Trial Programs.

During July, the PHE Conference Call will focus on AIDS Patient and Family Education activities and programs. This conference call is directed to all VAMCs and will highlight effective PHE activities and programs.

In addition, the OAA conducts monthly bibliographic citation searches on AIDS and distributes this information to Regional Medical Education Centers (RMECs), Cooperative Health Manpower Education Program (CHEPs), and chairpersons of VAMC PHE Committees. A search for audiovisuals related to AIDS has been conducted and distributed to RMECs.

Dr. GRONVALL. Mr. Chairman?

Chairman CRANSTON. Yes?

Dr. GRONVALL. There has been a good deal of discussion today about statistics and the need to clarify the record. If I may, I would like to make a comment on an earlier statement made here that, at one of our Veterans' Administration hospitals, something like one-third of the patients in the hospital have AIDS. I believe I can correct that.

Chairman CRANSTON. I don't believe I meant to say that.

Dr. GRONVALL. No, it was said earlier. And again, in the interest of having an accurate public record, I ask to correct that. The hospital being referred to was our New York hospital, I believe—Manhattan. That hospital has had the greatest incidence of AIDS. Recently, we have surveyed all of our hospitals, and the Manhattan hospital, at any one time, will have something like 20 AIDS patients hospitalized in the hospital. That hospital has some 600 beds, and that figure of 20 AIDS patients then, compared to the total hospital bed complement, would result in something like 3 percent of the total patients in that hospital being hospitalized for AIDS. We do not have any hospital that approaches 30 percent of its patient population having AIDS.

Chairman CRANSTON. Good. John, the ANA's written testimony cites reports that a list of VA patients tested for HIV was found in an accessible photocopy at a VA facility after it was inadvertently left there. Do you know of any other incidents like that?

Dr. GRONVALL. I have not read that testimony, and I was wholly unaware of the incident referred. And I have not had any report made to me that there has been any breach of confidentiality of the record system in the VA. So, I will certainly look into that. That is the first I have heard of such a case.

Chairman **Cranston**. If that is true, let me ask you, why would such a list be compiled and why would it be photocopied?

Dr. **Gronvall**. Of course, I don't know the answer.

Dr. **Cohn**. I have no answer.

Chairman **Cranston**. Will you endeavor to find the answer to that?

Dr. **Gronvall**. We absolutely will. As I said, I was unaware of that, but we will surely followup on that immediately. I am very anxious to continuously take steps to protect the confidentiality of our records. I appreciate anyone bringing a problem to our attention, and we will immediately followup on it.

Chairman **Cranston**. That is one that obviously needs explanation.

Dr. **Gronvall**. We absolutely will.

[Subsequently, the Veterans' Administration furnished the following information:]

An investigation is underway, and we will provide the results of that investigation when available.

Chairman **Cranston**. John, the city of San Francisco has developed a very successful model for caring for AIDS patients. It provides a continuum of care which includes home and other community-based noninstitutional care and hospice care, but it has no long-term beds available for AIDS patients.

Do you have plans to develop a strategy for meeting long-term institutional care needs of veterans who have AIDS?

Dr. **Gronvall**. Yes, we have worked on that; and it is part of the planning activity that I referred to that needs to be strengthened in the VA. I think each of our medical centers that experiences a heavy volume of AIDS-related patients is searching for the best way to approach this very difficult disease, and we are hoping to work out ways in which we can document and test different approaches, including the one that you described.

Chairman **Cranston**. I assume you know there is an effort under way in Congress to transfer from the Army to the city of San Francisco the former Public Health Service Hospital there that was returned to the Army back in 1981. If this transfer goes through, the city would utilize the hospital as a nursing home and other long-term care needs for AIDS patients. If such a facility is indeed established in San Francisco, do you believe that the VA might be interested in entering into an agreement with the city of San Francisco whereby the agency would be able to utilize some of the nursing home and other long-term care capacity of the facility for VA AIDS patients? It seems to me that you are going to need long-term care beds for AIDS patients in San Francisco, and there are virtually no such beds available in San Francisco.

Dr. **Gronvall**. Yes, you are certainly right. I am aware only generally of that proposal, but we would be very anxious to be part of that deliberation. And wherever we have a documented need for such extended care beds, that kind of potential would be of great interest to us and the kind of general relationship you describe where we contract for that kind of care is something that we would be anxious to explore and do, if it could serve the purpose of facilitating care of veterans.

Chairman **Cranston**. This may be a question again for Mr. Ibson, but do you believe that you have sufficient legal authority to enter into that kind of agreement?

Dr. **Gronvall**. Yes, I believe so, but that is a very general answer; and again, it would depend on the particular eligibility of the individual veteran.

Chairman **Cranston**. Dr. Curran, if I could turn to you, with regard to the same issue, the Army has recommended that, instead of it directly leasing the facility to the city of San Francisco, it turn the facility over to the Public Health Service which would, in turn, lease it to the city. Since the facility will be used as a health care facility, I think that that proposal makes good sense. The facility represents a unique opportunity to learn about extended care needs and programs that will be increasingly in demand as this epidemic worsens. I would very much hope to have the department's cooperation on that issue. Could you ask Secretary Bowen for his views on the feasibility and advisability of such a proposal, and get back to us in the next few days with his response?

Dr. **Curran**. Yes.

[Subsequently, Dr. Curran provided the following information:]

In an April 14, 1987 memorandum from Assistant Secretary Dr. Robert Windom to Dr. Sheridan L. Weinstein, PHS Regional Health Administrator for Region IX, regarding the potential use of the former San Francisco Public Health Service Hospital as a facility for the care of people with AIDS, Dr. Windom stated:

"I do not see the return of the PHS Hospital to a federally managed facility as a feasible option. However, I feel that if the City and County of San Francisco either alone or in cooperation with neighboring health departments would be interested, they might pursue options for use of space in the building as a subacute care facility for people with AIDS." Because responsibility for the building now rests with the Department of Defense, Dr. Windom stated further: "Whether space in the building could be secured from the Army is another matter which the San Francisco health officials would have to address once they have formulated a plan for its use."

[Note.—On December 4, 1987, the President signed Public Law 100-180, the National Defense Authorization Act (H.R. 1748) which includes a provision directing the Secretary of the Army to lease the former Public Health Service facility to the City and County of San Franscisco for an AIDS/ARC treatment center. According to the statement of the congressional conferees on the legislation, the lease will be entered into no later than January 1, 1989.]

Chairman **Cranston**. John, back to you. On an unrelated but not totally dissimilar issue, drug testing of VA health workers, I am deeply concerned that the VA not move ahead in any new testing program without first providing this committee a full description and cost estimate of the program.

I would also urge that the VA's testing program be carried out in full compliance with criteria that all other Federal agencies must adhere to. And finally, I believe that no testing program should be implemented at the VA unless there is a specific appropriation for that purpose. Funds should not be siphoned off from direct patient care programs for the purpose of testing VA employees. I will likely pursue legislation to effectuate these three purposes regarding VA employee drug testing.

What is your current policy with regard to drug testing of DM&S employees and applicants for employment generally, or in a particular program like substance abuse?

Dr. **Gronvall**. As a general statement, we are working, of course—along with other Federal agencies—to develop a description of an expanded drug testing program that might be put into effect for employees within the VA. I am unaware at the present time of any drug testing program that operates within the Veterans' Administration, although it has been brought to my attention that in some our drug abuse programs there is screening of people working in the drug abuse program. I don't have definitive information on that. Dr. Cohn, could you help me?

Dr. COHN. I have no more data.

Dr. GRONVALL. As I say, we are developing a plan for the capability of an expanded drug testing program, which has not been put into operation as yet.

Chairman CRANSTON. Further, on health employee drug testing, what are your personal and professional views about drug testing on each of the following points? First, should testing be conducted routinely on all DM&S employees or only based on reasonable suspicion?

Dr. GRONVALL. I do not believe that it would be appropriate to conduct drug testing on every employee in the Department of Medicine and Surgery. I believe the purpose of drug testing is to focus on individuals whose level of responsibility or activity or whose behavior or work performance is such that it is important to assure that the person is not under the influence or using drugs; and so, the testing should be targetted or focused in that way.

Chairman CRANSTON. If routine testing were to be pursued, should it be random or announced?

Dr. GRONVALL. Again, that is a question I don't think I can answer with a very substantive answer because it depends on the purpose, I think, of the testing. And I think in some instances, there is a rationale for random or unannounced testing; but as a generalization, I believe testing is better done when it is announced and the individuals who are going to be tested know the purpose of being tested, and it is announced in a planned program.

Chairman CRANSTON. How often should Government employees be tested?

Dr. GRONVALL. Again, that is a question that I don't think I can answer. It depends upon the particular kind of drug and the individual circumstance as to how often there needs to be assurance or a repeat look to see whether the person is free of the influence of drugs.

Chairman CRANSTON. Is there any reason to believe that drug abuse is a significant problem among VA health care workers?

Dr. GRONVALL. I have no reason to think that there is a unique kind of problem among VA health care workers. Our staff, of course, come from the general population; and so, the drug abuse problem in America means that we are not immune to that problem among our employed staff. We judge the quality of performance of every one of our staff, and so we judge people primarily on their performance. And I am not aware of either any data or assertion that we have a particular problem in the VA.

Chairman CRANSTON. Do you have a personal or professional opinion on the efficacy of testing for drugs but not for alcohol?

Dr. GRONVALL. I think I don't quite understand the context of that question.

Chairman **Cranston**. Does it make sense to test for drugs but not for alcohol?

Dr. **Gronvall**. If the purpose of testing is to gain assurance that individuals who are taking care of veterans are not under the deleterious influence of a substance, then alcohol abuse and drug abuse certainly fall under the same banner and can have the same negative effect on the person's ability to do a job. So, in that context, both are of great concern.

Chairman **Cranston**. Thank you very much. Dr. Curran, it is clear that there is heavy pressure from OMB, the Domestic Policy Council, and elsewhere in the administration, with regard to this testing issue. The Secretary of Education and others without public health backgrounds or operational responsibilities are taking firm public positions in sharp variance with what leading public health authorities are meanwhile advising. I think that, in this time of great anxiety, the American public needs to know that it is getting the best possible advice from our public health officials, and that it is advice based on sound public health policies, untainted by any political considerations.

The CDC has a hard-won reputation as a reliable source of sound scientific judgment, unmixed with political concerns.

It has consistently been a voice of reason. It has consistently given guidance and assistance on the most controversial issues that have arisen concerning AIDS. For instance, whether children of AIDS should be excluded from schools and what steps health-care workers should take to prevent exposure to the HIV virus. I was very pleased that when the issue of mandatory testing first came up, CDC held a conference to hear differing viewpoints and to reach a concensus on the appropriateness and feasibility of various testing programs. I think CDC was able to make some very sound recommendations as a result of that conference, and I am confident that we can continue to count on you for that type of courageous and needed leadership.

There will be many times in the weeks and years ahead when those of us in political positions will be confronting policy decisions with respect to testing, discrimination, and possibly even quarantine relating to AIDS. In those situations we will be looking to our public health officials for their counsel as to what courses of action are wisest from the public health standpoint.

We must be able to get that advice straight, if it is to be of value. If the advice we get is skewed by political considerations before it emerges, I then would be concerned that we could be misled into making some mistakes that could be disastrous. Dr. Gronvall, as that story on the front page today of the New York Times makes clear, the same is true with respect to the VA. I believe that you are under the same kinds of pressures, and I congratulate you on the strength of character and leadership that you are displaying on these issues, which I know are very, very tough to handle.

Now, I would like to ask Dr. Curran about a report issued by the CDC on April 30, 1987. That report entitled "Recommended Additional Guidelines for HIV Antibody Counseling and Testing and the Prevention of HIV Infection in AIDS," presented a summary of proceedings from a February meeting on that subject, as well as

CDC's recommendations that evolved from the meeting. Is it correct that that report has not yet been formally approved?

Dr. Curran. That was the CDC report to the Public Health Service.

Chairman Cranston. Did Dr. Windom approve it?

Dr. Curran. I believe it is under consideration by the Public Health Service.

Chairman Cranston. What about Dr. Bowen?

Dr. Curran. He is Dr. Windom's boss.

Chairman Cranston. Yes. So, there has not yet been an approval there?

Dr. Curran. It has been submitted.

Chairman Cranston. Has it been submitted to the OMB for approval?

Dr. Curran. I don't know. I think it is in the Public Health Service being considered.

Chairman Cranston. Could you find out if it has gone to OMB or if it is scheduled to go to OMB?

Dr. Curran. The answer to both these questions is no.

Chairman Cranston. Dr. Curran, in the April 1987 CDC document on testing and counseling, the CDC calculated, I believe, that at a minimum it would cost more than $18,000 to detect and counsel a single infected person through routine screening of low risk populations. Is that a correct estimate?

Dr. Curran. I think you can take the $5 average and if you have a population where 1 per 1,000 is infected, it is $5,000. Counseling would add another $25 to $45 to that. So, even in a population of 1 per 1,000, you are talking about numbers in excess of that.

Chairman Cranston. What would be the total figure then? Do the mathematics for us.

Dr. Curran. You probably have a copy of the report. You may be more familiar with it than I am—the details of it. If you can give me the page number——[Laughter.]

I think it was page 4 in the draft.

Chairman Cranston. Their estimate was $18,000 to detect and counsel a single infected person through routine screening of low risk populations. Do you consider this to be a cost-effective method for reaching and educating people about AIDS?

Dr. Curran. I believe that dealing with infected individuals—the low risk is 1 in 10,000——

Chairman Cranston. What is that?

Dr. Curran. I believe that routine testing and counseling of moderate to high prevalence populations is perhaps the most important thing we can do. Now, your question about the substance abuse programs, those allow us to find people, many of whom demonstrate addictive behavior and who need—in addition to testing and counseling—readily available drug treatment. Many people in the heterosexual populations, like their spouses, and many people in minority communities are totally unaware that they have been infected with the virus.

There was a study presented at the International Conference on AIDS by Dr. Menkoff and Dr. Landesmann, where they tested pregnant minority women living in Brooklyn—at one hospital in Brooklyn—and 2.5 percent of the women were infected with the virus.

They had to do the test on a research basis at the time. Most of these women had no idea that they were at risk and they were already pregnant. That is important information when these women consider their next pregnancy and when they consider family planning.

Therefore, particularly in the populations where people have no inkling that they might be infected, I think it is probably not too much money to spend. It is related to what is going to happen after the test result, the availability of the resources to make that happen. So, I think whether it is $18,000 or $8,000 or $4,000 is not as important as what you are going to do when you get positive results. Then there are going to be some additional expenditures there.

Chairman CRANSTON. I take it that you feel that routine testing of low risk segments of the population is not a good investment?

Dr. CURRAN. I think we don't know very much about the prevalence in most settings. We don't know just exactly what we will find when we do much of this routine testing. People were very, very surprised to find that 2.5 percent of the pregnant population in Brooklyn, for example, even though it was predicted. I think many hospital settings could do surveys to find out—whether they are anonymous or blind surveys—as we are doing in some 10 or 12 sentinel hospitals around the country—and see what the prevalence really is.

Chairman CRANSTON. I felt that Senator Murkowski wasn't getting guidance from you in his effort to get guidance on what is a very delicate and important point that he was pursuing. And that is, where there are high risk groups that may well be infected, many individuals don't know it and are, therefore, quite possibly spreading the contagion to others quite innocently. What can be done to reduce that risk? How do we go about persuading those people to be tested so that they can take precautions to protect others? That was the point that was concerning Senator Murkowski, and it is an obvious, legitimate concern.

Dr. CURRAN. I think it is easy to discuss whether mandatory testing should or shouldn't be done and whether other measures ought to be taken, but we have to sit back and ask ourselves why it isn't being done. It isn't just because some people are for it and some people are against it; and the people who are against it are winning, and the people for it are catching up. It is more of a question of what it takes to do it.

Let's say there are 100,000 people in substance abuse treatment programs in the United States that are under State and local control through block grants and have a certain amount of medical care available to them. Some of the counselors in these programs are people who used to be patients, and they are already overwhelmed. And 25 percent of the patients are infected with the AIDS virus. How do we get to making sure that every single person is tested and gets adequate medical care in those communities and all of their families get tested and get adequate medical care and family planning services and things like that? Some people are afraid to go in those neighborhoods. I mean, it isn't as simple as just being for it or against it. It takes a real bipartisan, nonpolitical commitment to do it.

Chairman **Cranston**. To do what?

Dr. **Curran**. To provide testing, counseling, and medical care for all infected people. There will be resistance to it, but I think if people felt that at the end of every test there was a doctor, instead of a loss of job or loss of insurance, they would be more willing to do it.

Now, not everybody would be willing to do it, but I would rather see a doctor at the end of every test than a pink slip.

Chairman **Cranston**. Dr. Curran, in regard to the demographics of VA patients, do you consider them representative of the general population and, thus, a good source of epidemiological data regarding the spread of the virus in our population?

Dr. **Curran**. I think generally yes; subtlely, no, in the sense that the AIDS patients themselves have included all aspects of the general population; but the patients in the VA hospitals have been heavily weighted toward men who are more likely to be veterans, as opposed to women. They have been more weighted toward Black and Hispanic minorities than AIDS patients in the general population and more weighted toward people with a history of IV drug abuse as the risk factor as opposed to homosexual transmission. In the latter regard, I think it is filling a need even if the data is disproportionate.

Chairman **Cranston**. Do you believe that the three recently reported incidents in which health-care workers became antibody positive after exposure to blood could have been prevented by adherence to the CDC guidelines?

Dr. **Curran**. I think all transmissions are not going to be prevented by the adherence to guidelines, simply because everyone isn't going to adhere; and that is human nature. In the three most recent cases that were reported, two of the health-care and laboratory workers were not wearing gloves. One of the nurses was trying to save the life of somebody in an intensive care unit in a hospital where there had been no cases of AIDS previously. The person could not have been tested because the patient just came in and died.

To say that this person should have put on gloves before she did the lifesaving maneuvers, I think, smacks of blaming the victim, in my opinion. On the other hand, a couple of the other cases and many of the needle stick cases have resulted from people not either knowing or following precautions such as recapping needles or handling blood without gloves on and things like that—coming into contact with body fluids.

Chairman **Cranston**. Do you think that health-care workers should adhere to those guidelines as a matter of course in treating all patients?

Dr. **Curran**. Absolutely. I think that one benefit that we have seen from concern about AIDS has been the increased compliance of dentists and hygienists with wearing gloves and masks. I had observed over the last 6 years a tremendous change in my own dentist and hygienist, and I think many of us have. That will also prevent a lot of Hepatitis B and other infections. There has got to be a lot more training for health-care workers in this area.

Chairman **Cranston**. John, would that be your view also?

Dr. **Gronvall**. Absolutely.

Chairman **Cranston**. Dr. Clinton, does the department require that any pretest counseling be provided to any individual to whom the test is being administered?

Dr. **Clinton**. Yes. It is very clear that there is an education process prior to the testing of the active duty individuals, as well as a post-test, both evaluation and counseling. Often times, if you look at how that is done on the military base, there is a meeting of a battalion or a group of individuals, and there is information about what this program is, what we are trying to accomplish, how it is good for them, how it is good for the military. There may be a film; all services have films, some created by themselves. Others utilize films from the Public Health Service, the American Red Cross, and other sources.

And then, at the end of that information program, the testing is actually accomplished where blood may be drawn on, say, 100 individuals at one time and then sent to the contract laboratories. That is a long way of explaining how it is done; but as you would expect in the military, it is usually done in group batches if you will.

Chairman **Cranston**. What goes on in pretest counseling for recruits?

Dr. **Clinton**. That is fairly minimal since they are simply showing up, and they are advised that they are going to be tested for that. I think that there is not a great deal done with regard to the implications of it.

Chairman **Cranston**. What about post-test programs?

Dr. **Clinton**. They are advised to seek local assistance wherever that may be. Since these are not beneficiaries of the Department of Defense, we are troubled with that problem and have only been able to help the individual find assistance through the family physician. Of course, there won't be any in a number of cases since community resources for counseling are growing in the areas where the prevalence of the disease is highest, then community resource assistance usually can be arranged; but we are aware of significant difficulties in that regard.

Chairman **Cranston**. You wouldn't cover the cost of any counseling by the family physician?

Dr. **Clinton**. No.

Chairman **Cranston**. Would you supply for the record all the copies of policy directives that relate to counseling that you have issued?

Dr. **Clinton**. Yes.

[Subsequently, Dr. Clinton furnished the following information:]

The relevant portion of the DoD Policy on Identification, Surveillance, and Administration of Personnel Infected With Human Immunodeficiency Virus, dated 20 April 1987, follows:

(a) Upon notification of an individual with serologic or other laboratory or clinical evidence of HIV infection, the cognizant military health authority shall undertake preventive medicine intervention including counseling of the individual and others at risk of infection such as his or her sexual contacts (who are military health care beneficiaries) regarding transmission of the virus, coordination with military and civilian blood bank organizations to trace back possible exposure through blood transfusion or donation of infected blood, and referral of appropriate case-contact information to the cognizant military or civilian health authority.

(1) All individuals with serologic evidence of HIV infection who are military health care beneficiaries shall be counseled by a physician or designated health care provider regarding the significance of a positive antibody test. They shall be advised

as to the mode of transmission of this virus, the appropriate precautions and personal hygiene measures required to minimize transmission through sexual activities and/or intimate contact with blood or blood products, and of the need to advise any past sexual partners of their infection. Women shall be advised of the risk of perinatal transmission during past, current and future pregnancies. The beneficiary shall be informed that he or she is ineligible to donate blood and shall be placed on a permanent donor deferral list.

(2) Epidemiological investigation shall attempt to determine potential contacts of the patient with serologic or other laboratory or clinical evidence of HIV infection. The patient shall be informed of the importance of case-contact notification to interrupt disease transmission and shall be informed that contacts will be advised of their potential exposure to HIV. Individuals at risk of infection include sexual contacts (male and female), children born to infected mothers, recipients of blood or blood products, organs, tissues, or sperm, and users of contaminated intravenous drug paraphernalia. Those individuals determined to be at risk who are identified and who are eligible for health care in the military medical system shall be notified. Military members identified to be at risk shall be counseled and tested for serologic evidence of HIV infection. Other beneficiaries, such as retirees and family members, identified to be at risk shall be informed of their risk and offered serologic testing, clinical evaluation, and counseling. The names of individuals identified to be at risk who are not eligible for military health care shall be provided to local civilian health authorities unless prohibited by the appropriate State or host nation civilian health authority. Anonymity of the HIV index case shall be maintained unless reporting is required under paragraph 5.b.

(b) Communicable disease reporting procedures of civil authorities shall be followed to the extent consistent with this memorandum through liaison between the military public health jurisdiction and the appropriate local, State, territorial, Federal, or host-nation health jurisdiction.

Chairman Cranston. What plans does the department have for the distribution of the Surgeon General's Report on AIDS to service persons and civilian personnel?

Dr. Clinton. The written testimony provides some reference to that. We have already distributed several thousand and have ordered several thousand more. More importantly, we have also developed materials that are complementary to that same message in various forms in all three services. We are spending literally hundreds of thousands of dollars on various information materials directed to the community and directed to the individual. Included in that is Surgeon General Koop's message.

Chairman Cranston. On page 11 in your testimony, you state that policies involving screening of the family members of military personnel and civilian employees, prior to being sent overseas under military sponsorship, will be developed as necessary by the Assistant Secretary of Defense for Management and Personnel. Is that policy for mandatory testing for family members and civilian employees, prior to being sent overseas, now under consideration?

Dr. Clinton. There are those who have raised it. That was a more active debate, I would say, several months ago than it is today. There are no immediate plans to do anything. There are those who believe it is the right thing to do—similarly to what we hear along the lines of mandatory testing in the United States. I don't think sufficient rationale has been developed. It certainly hasn't even come to my attention yet—for a definitive statement.

Chairman Cranston. What are active duty personnel specifically told with respect to the use of condoms?

Dr. Clinton. They are told that it minimizes their risk, if they choose to have sex. They are told that abstinence is also useful to stem the spread of the disease. More specific to your point, we are not using the term "safe sex." We are saying it minimizes risk, if they continue to have sexual contact.

Chairman CRANSTON. Why are condoms not now being sold at military commissaries?

Dr. CLINTON. Because they are widely available in other sources, such as the exchange.

Chairman CRANSTON. Don't you think we should be doing everything possible to make them available?

Dr. CLINTON. Yes, and that is under consideration. I think commissary systems are constrained to sell only so many products, and it means something else will come off the shelf. Commissaries are there to provide predominantly food products, as you well know. I understand that that is being discussed; I have not yet seen them in the commissary.

Chairman CRANSTON. Is there any discussion of dispensing condoms without charge?

Dr. CLINTON. No serious discussion.

Chairman CRANSTON. Would you report back on what discussions are going on?

Dr. CLINTON. I am not aware of any. I hear a whole lot of talk, but there have not been any formal discussions.

Chairman CRANSTON. On the commissary business?

Dr. CLINTON. I will provide that.

Chairman CRANSTON. Thank you.

[Subsequently, Dr. Clinton furnished the following information:]

We stock prophylactics in military exchanges, but not in commissaries. The DoD Resale Executive Board, composed of the Services' Exchange and Commissary Commanders and representatives of the Office of the Secretary of Defense meets several times each year. At these meetings, general stockage policy is a frequent agenda item. At the meeting in April 1987, the specific issue of stocking prophylactics in commissaries was discussed at length. The DoD Resale Executive Board decided to continue current stockage policy. The rationale for the Board's decision was that the need to have this product available on military bases was being met by the exchanges. The Resale Executive Board pays close attention to the balance of products sold in commissaries and exchanges, which has been carefully developed based on the different missions of the two resale activities.

Chairman CRANSTON. Colonel Bancroft, in the Defense Department's testimony, you indicate that $37.8 million was appropriated in fiscal year 1986 for AIDS research, and $21.8 million for fiscal year 1987. At a time when the research budget for AIDS is increasing at NIH, why did the President's budget include only $5 million for DOD AIDS research for fiscal year 1988?

Colonel BANCROFT. I have asked the same question myself. I think that it is insufficient, but the first two appropriations—the fiscal year 1986 and the fiscal year 1987 appropriations—were supplemental appropriations. And they came to us late in the fiscal year. For instance, the fiscal year 1986 money came to us in August of 1986; the fiscal year 1987 money is coming to us in June—this month—for use, which we do have permission to obligate this money over the second year. But it still curtails the period of time in which we would ordinarily be able to utilize the money, and it takes a little longer to establish a new research program than it does to commit money and obligate money for an established research program.

At this point, the DOD HIV research effort is still in the beginning stages. Nevertheless, of the fiscal year 1986 money, essentially all of that has been obligated already; and the fiscal year 1987 money is well planned. For fiscal years 1988 and 1989, we are in the DOD budget; and as you say, we are programmed to have $5 million for fiscal year 1988, which I assume will then come with the rest of our research money toward the beginning of the fiscal year and will get us into a more regular fiscal policy.

Chairman CRANSTON. Is there any effort under way to get a more adequate amount?

Colonel BANCROFT. We have sought additional funding. The most difficult year will be for fiscal year 1989, when we only have $12 million for the program. Much of our fiscal year 1986 money has gone to extramural contracts. In fact, almost $30 million of it has gone on to extramural contracts.

In many of these cases, the contracts can be funded for up to 3 years. Those will come up for renewal in 1989, at a time when we only are going to be or are already underfunded.

Chairman CRANSTON. Colonel, out of that total of nearly $60 million combined for AIDS research funded by the Army for fiscal years 1986 and 1987, only $2.4 million has gone to VA researchers. Given the number of AIDS patients being treated by the VA, the VA's relationship to a national defense mission, and the VA's great potential for cooperative research programs, wouldn't it be beneficial from the standpoint of finding more effective treatments and possibly a vaccine to increase the research collaboration between the VA and the Army?

Colonel BANCROFT. We certainly are looking for any opportunity to expand the research cooperation between the VA and the Army. As with all the other extramural contracts and grants, these are submitted to us for scientific review and are judged on scientific merit. The two awarded contracts were considered highly meritorious, and they are certainly program-relevant. They are relevant to the goals of our research program.

Chairman CRANSTON. I just have, finally, a few questions on a topic we have not yet discussed this morning: confidentiality rules regarding partners. In the case of a hospital or clinic—Dr. Curran this question is for you—where a patient tests positive and is symptom-free, do you believe that it would be helpful from the standpoint of confidentiality not to include the test result in the patient's medical record?

Dr. CURRAN. I think that is a tough one; that is why you asked it. I think, under an ideal circumstance, it is important for all medical personnel with a need to know, to know that the patient is HIV positive. And in many hospitals where you don't have a private physician—and I think the VA system would probably fit into that—a person may see a different doctor the next time they come in. They also may see a different doctor in a different service. Having HIV infection is very important and having your doctor know it is important.

So, I think that many physicians, nurses, and others will need to know that a person is infected with HIV. On the other hand, there are liability issues as well as confidentiality issues for the hospital and doctors involved. I think that this is a real policy matter, when it comes to maybe setting up a separate system for HIV results, with some sort of theoretically secret flag that indicates someone should check the separate system out. However, all that usually becomes known by too many people.

I think we could ask DOD. DOD has done this; how did they handle this? It is a tough one.

Chairman **CRANSTON**. Do you have a comment?

Dr. **CLINTON**. We believe it should be in the medical record.

Chairman **CRANSTON**. John, what is your feeling? There is the question obviously of confidentiality.

Dr. **GRONVALL**. My general feeling is that this is highly important medical information that should be in the record, that we should protect the confidentiality of those records; but the reason for my making that statement is that, if the individual is in fact infected, I would hope that our team of health care professionals working with the patient—and that includes doctors, nurses, counselors, social workers, chaplains, et cetera—would be able to assist the veteran in understanding that a change of behavior or working with the veteran's spouse or contacts is important, so that we get the maximum patient cooperation in doing whatever can be done to deal with the problem that exists.

So, I believe it is relevant medical information. I surely am extremely concerned about the problem that occurs when information leaks. And in fact, one of my very great concerns is that, under existing circumstances, we can and in fact do disclose medical information to insurance companies which they require in order to validate the bills that we submit to collect for care of veterans, as authorized by current law. And this raises a real dilemma for us of disclosing to a third party, reimbursement, or insurance company such highly sensitive medical information.

I would echo Dr. Curran's comment that this is a very tough question. There is no easy answer, and I have tried to portray an objective of medical care; but it surely is not a simple question.

Chairman **CRANSTON**. Dr. Curran, if I may ask you this question? What procedures do you consider to be appropriate for notifying spouses and/or steady sex partners?

Dr. **CURRAN**. With many other sexually transmitted infections, people who are counseled often choose to notify their own spouses; and I mention this first because the question usually comes up: What do you do in the cases where that doesn't happen? But we have to emphasize that often this works. People bring their own spouses or steady sex partners in for counseling and testing. I think this needs to be exploited and used as much as possible. It takes fewer resources and is more humanistic.

Second, many people prefer that public health representatives or medical representatives inform their spouses; and that is sort of the second approach taken in many public health departments. The patient will say: here is the name; please help me. Now, that is a little bit of a problem for nonsteady partners because that could be misused by people; and it involves the voluntary nature of the informant, if you will—the person who is infected .

There are selected circumstances when the patient may not want the spouse to know. Then the doctor or the public health person will be in a dilemma; and they may be in a legal dilemma. Dr.

Myers, one of your later witnesses, and I were discussing this the other day—what we personally feel.

A man comes in and he is positive for HIV. He says: I don't want my wife to know; she will divorce me and I will lose my job, and it will ruin my standing in the community. What do you do? Well, there may be a law in some States that says you can't release this information; otherwise, you will go to jail. There may be another law that says if you don't tell the person, then you go to jail. So, the doctor knows first of all that he might end up in jail. So, you are back to what do you think ought to be done ethically? And I personally think that the doctor ought to call the spouse.

Chairman **CRANSTON**. John, does the VA have any policies or do you have any views on that?

Dr. **GRONVALL**. We have both policies, and I have views. [Laughter.]

Dr. **CURRAN**. Are they the same?

Dr. **GRONVALL**. And they generally are the same. [Laughter.]

I would align myself with virtually everything Dr. Curran said. I would emphasize the very difficult nature of that dilemma. Our current policy, I think, is very clear. We work with the patient and we only inform either the spouse or anyone else about the existence of AIDS infection or AIDS when we have the patient's consent to do so. That policy for AIDS is the same as our policy for any other disease or other medical problem that a veteran patient has. In most cases, of course, we gain the cooperation of the veteran—in this case with AIDS—and that is the purpose of what I have been describing as the need to work collaboratively and cooperatively with an ill individual, to gain that person's trust and confidence, and to allow us to work with that veteran to inform the spouse or other sex partner so that they can take appropriate steps to protect themselves. But in that very unusual test case, and I am sure we will be tested—in fact, are being occasionally tested—our policy is quite clear. If we do not have consent from the veteran to inform anyone else of the nature of the individual's medical problem, we do not carry that out.

Chairman **CRANSTON**. Yes, Dr. Curran?

Dr. **CURRAN**. I think the clearest and easiest way to see this issue is how the National Hemophilia Foundation and hemophilia treatment centers have dealt with this problem. They have a substantial portion of their constituents infected with the virus, all men, and many of whom are married or have steady sex partners. Over a period of time of quite intensive education and counseling and concern about AIDS, they have moved along—over the 2 years since the test has been licensed—to a policy of recommending routine voluntary testing and counseling of all of the family members.

That is something that is quite a traumatic experience. It is easiest to think of this in the context of the family unit; but most people who talk about this issue are talking about it in other contexts. In the families of hemophiliacs, there is no question about how the hemophiliac became infected. So, it becomes even more difficult when there is a concern about the behavior of the person or hidden homosexuality or drug abuse.

Dr. **GRONVALL**. I would add, if I might, Mr. Chairman, that Dr. Curran stated he has an ethical belief as a physician that the physician should inform the spouse. I agree with that as an individual physician. My comments, though, are in the perspective of a health-care system which is, in fact, an arm of the Federal Government and where policy and procedure have to be tested against the other implications of having an official Federal policy or procedure.

So, as I said, at the present time, our policy is quite clear that, in the absence of consent, we don't make such disclosures in any case about veterans other than under a very clearly defined condition such as a request from this committee, duly established requests for such information.

Chairman **CRANSTON**. I want to thank you all very, very much. You have been very patient and very responsive. You have been very, very helpful, and I am deeply grateful to you.

Dr. **GRONVALL**. Thank you very much.

Chairman **CRANSTON**. We will now go to the public health panel, consisting of Ms. Mary Foley, San Francisco, Chairman of the Cabinet on Economic and General Welfare for the American Nurse's Association, accompanied by Thomas Nickels, Director of Congressional and Agency Relations, and Ms. Donna Richardson, Assistant Director of Congressional and Agency Relations. Other members of the panel are Dr. Woodrow Myers, Jr., Indianapolis, Indiana State Health Commissioner and President of the Association of State and Territorial Health Officials; Ms. Ann E. McFarren, Executive Director, AIDS Action Council; and Dr. Paul Schafer, Executive Director, National Association of VA Physicians.

We will start with Mary Foley. And Mary, I want to thank you for coming so far and welcome. If you would start, I would appreciate it.

STATEMENT OF MARY E. FOLEY, CHAIRMAN, CABINET ON ECONOMIC AND GENERAL WELFARE, AMERICAN NURSES' ASSOCIATION, ACCOMPANIED BY THOMAS NICKELS, DIRECTOR, CONGRESSIONAL AND AGENCY RELATIONS; AND DONNA RICHARDSON, ASSISTANT DIRECTOR, CONGRESSIONAL AND AGENCY RELATIONS

Ms. **FOLEY**. Thank you, Mr. Chairman. As you indicated, I am accompanied today by Tom Nickels and Donna Richardson from the American Nurses' Association staff. I am a registered nurse employed as a staff nurse at St. Frances Memorial Hospital in San Francisco. On behalf of the 188,000 members of the American Nurses' Association and its 53 constituent State nurses' associations, thank you for this opportunity to address the Veterans' Administration AIDS policy. ANA has 24 collective bargaining units in VA hospitals in long-term care facilities. There are 35,000 RNs and 32,000 other nursing personnel in the VA.

In essence, the American Nurses' Association believes that the most effective tools for preventing the transmission of AIDS are education and preventive health techniques. We oppose discrimination against persons with AIDS or a positive HIV. We support the availability of quality, confidential health care and respect for the affected individual, and we support increased funding for research and educational efforts. ANA has stated that all people who have AIDS have a right to equitable and humanistic health care, including quality treatment which include nursing and social service support, the nondiscriminatory use of current isolation procedures, full explanations of research procedures, treatments, and risks involved, informed choice of treatment and research modalities, confidentiality of the medical records, and respect for privacy in significant relationships.

As we all know, presently there is no cure for AIDS, but it does respond to care. It is a disease that is nursing intensive. It is nurses who provide continuous care during the hospitalization, in the home, and in the hospice settings. Nursing has had a tradition of providing quality care to the victims of once fatal infectious diseases, such as poliomyelitis, yellow fever, and tuberculosis.

The nursing profession will take a leadership role in continuing to provide safe and effective care to victims with AIDS, their families, and their friends. ANA has recognized that education about the epidemiological aspects of the disease is not enough. The association participated in the revision of the CDC's "Recommendations for Preventing Transmission of Infection with HTLV 3 Virus in the Workplace" issued in 1985. We have repeatedly urged OSHA to address the hazards of AIDS and hepatitis, and since 1984, urged the NIOSH to release its document, which includes recommendations on employee exposure to AIDS. CDC has revealed that three health-care workers, including a nurse, have sero-converted after exposure to blood and body fluids of patients, subsequently revealed to be seropositive for AIDS.

ANA reaffirms its support of the CDC guidelines but believes agency enforcement is necessary to ensure employer and employee compliance. Recently, there has been an increased call for mandatory testing for AIDS by some legislators and the President, who recommended patients who receive care from the VA be tested. Although ANA agrees with the President's admonishment that those with AIDS not suffer discrimination, we differ with his recommendations on testing of hospital patients. In fact, we are more closely in agreement with Dr. Koop, who is quoted:

> Compulsory blood testing of individuals is not necessary. The procedure could be unmanageable and cost prohibitive. It can be expected that many who test negatively might actually be positive due to recent exposure to the AIDS virus and give a false sense of security to the individual and his or her sexual partners concerning necessary protective behavior.

The epidemiological benefits of testing do not support the redirection of resources from research and education to test a large body of people who are not high risk. Mandatory testing raises several concerns: First, costs for hospital patients alone have been estimated above $100 million. Second, the feasibility of providing the recommended counseling. Third, the issues regarding positive prenatal test results affecting birthing decisions. And last, the paramount concern of confidentiality of test results.

The latter issue raises particular concerns about discrimination in the areas of insurance, housing, and employment. Additionally, the result of testing all VA patients is that a multitude of documentation must be maintained, making the agency and the individuals vulnerable.

We have already heard a report that a list of the AIDS patients tested for HIV virus was found in an accessible copier after it was inadvertently left by someone hopefully performing official VA business. We shudder to think what the effect of the unofficial release of such information could have on a veteran's employment, housing, or insurance.

The VA is presently experiencing shortages of health-care personnel, and the testing and counseling of all veterans tested will additionally tax these resources. ANA urges the VA to use its resources for AIDS research and staff education and training. Caregivers to AIDS patients will need counselors to combat stress, burnout, and fear. Adequate staff will be necessary to guarantee quality nursing care but also to assure that nurses have the time and resources to comply with the CDC guidelines.

We would also like to take this opportunity to call for a national commission on AIDS with effective development and implementation authority. ANA did support S. 63 and urged that the VA be included in the legislative commission. ANA's June 1987 House of Delegates unanimously adopted a resolution on testing, which is included in our written statement. Most importantly, in summary, it does call for no universal mandatory testing and for informed voluntary testing and counseling, additional research, and a commitment to the rights of AIDS patients.

ANA pledges to continue its role in the community and the profession in promoting AIDS prevention and education. We hope that these hearings will result in a logical, scientifically based VA health policy on AIDS.

Chairman CRANSTON. Thank you very much.

Ms. FOLEY. Thank you.

Chairman CRANSTON. Dr. Myers.

[The prepared statement of Ms. Foley appears on p. 153.]

STATEMENT OF DR. WOODROW A. MYERS, JR., STATE HEALTH COMMISSIONER, STATE OF INDIANA, AND PRESIDENT, ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

Dr. MYERS. Thank you very much, Senator. I am Woodrow A. Myers, Jr., a physician and the State Health Commissioner of the State of Indiana. I appear before you today in my capacity as President of the Association of State and Territorial Health Officials. Our association is comprised of the chief health officials of the 50 United States, the District of Columbia, and the U.S. Territories. As State health officials, we hold leadership roles in public health in our respective States, both within the medical community and with our primary constituents, the citizens of our States.

Our association has worked closely with the CDC since the first days of the AIDS epidemic, and there continues to be a free, open, and frequent exchange of information and ideas between our association and the CDC. We have provided testimony before Senate committees and those of the House of Representatives on numerous occasions and are pleased to do so today.

There are several questions that I would like to summarize in my testimony. First, should the Veterans' Administration hospitals test entering inpatients and outpatients for the presence of human immunodeficiency virus antibody? Our association believes the answer is yes but with important caveats. First of all, we believe that testing and counseling are inextricably interwoven. And I am confident that our officials in VA hospitals are quite aware of that importance, and we have heard testimony to that effect today.

Our association also believes that counseling and testing are not necessary for every patient in the VA system. We know a great deal about the demographics of this disease and the behaviors that put individuals at risk. Cost effectiveness would be enhanced by physicians' selection of those outpatients and inpatients who fit the demographic profile of a seropositive patient or who, in history taking, admit to behaviors that put them at risk.

For instance, the World War II veteran admitted for multiple episodes of congestive heart failure—a typical VA admission—need not be counseled and tested unless specific behavior has put him or her at risk or blood transfusion occurred prior to the start of antibody testing protocols in our blood banks. Similarly, we do not believe that a patient who is tested and counseled at one point in time needs to be tested and counseled at every single contact point with the hospital in the future. The patient's risk status should be reassessed and, if retesting or additional counseling are indicated, they should be provided as necessary.

Should patients in the VA system have an option for refusing HIV testing and counseling, even when clearly indicated? In the United States thus far, we have held to the premise that an individual has the right to be informed of the care that they can and should receive and that an individual has a right to refuse such care.

The question is whether or not the HIV epidemic warrants a change in that philosophy. Our association believes that a modification, rather than a wholesale change, of that philosophy is indicated. Most physicians feel strongly that HIV testing and counseling needs to be effectively integrated into our normal, regular system of health care.

When we design systems and approaches that isolate HIV related disease from other diseases, inefficiencies and distortions occur. For instance, I am not aware of any hospital that requires a separate written informed consent form for VDRL, a blood test that determines syphilis, for the detection of the organism that causes gonnorhea, or for the detection of the presence of hepatitis B surface antigen.

With each of these diseases, there can be associated societal or informant related stigma, albeit less severe than that affecting the AIDS patient. Yet there has been no cry for a separate document or statement that patients have been informed of these tests and that these tests will be done and that they have accepted the risk of having those tests performed. In some hospitals, procedures akin to surgery, such as insertion of catheters into the heart, procedures with a degree of medical risk that far exceeds the medical risk involved in the collection of a tube of blood to determine HIV status are performed without a separate consent form being obtained.

The primary reason for informed consent is for the patient to understand the risk associated with a given medical act. There is virtually no medical risk from the collection of a sample of blood to determine HIV status. Therefore, those of us who are proponents of informed consent for HIV are in essence telling our patients that some members of our society may act on the information surrounding their HIV status; and our system of confidentiality may not be sufficient to protect them from such action.

As members of the committee may be aware, several States have passed statutes mandating that patients sign explicit informal consent forms prior to the collection of blood for HIV antibody testing. It is the concensus of our association that, given the perceived shortfalls in our systems of confidentiality and given the real threat in some States of individuals losing employment, housing, and insurance coverage, that an explicit right of refusal for HIV testing and counseling should be a part of any testing program base, either in the Veterans' Administration hospitals or in other hospitals or clinics. As a physician, I must tell you that it bothers me a great deal that my colleagues in public health must take a position like this in 1987, a position that says in effect we cannot trust the system to treat patients with this disease with the humanity and the compassion that other patients receive and that all patients deserve.

There are other aspects to our testimony that are within the written portion, and I would be happy to answer questions when appropriate.

Chairman Cranston. Thank you very much. Ms. McFarren?

[The prepared statement of Dr. Myers appears on p. 166.]

STATEMENT OF ANN E. McFARREN, EXECUTIVE DIRECTOR, AIDS ACTION COUNCIL

Ms. McFarren. Thank you, Mr. Chairman. I am Ann McFarren, and I am Executive Director of the AIDS Action Council. The Council represents over 300 community service organizations around the country.

I would like to focus my time with you on discussing the unique role that service providers around the country have offered in terms of managing this epidemic. We know that we now have over 36,000 cases of AIDS and that by 1991 we will be in the range of 270,000 cases. Before there was much attention either at the Federal level or in many states or cities, service providers identified serious problems and lack of health-care services and support as people confronted this terrible illness. As a result, new services and new types of programs were set up in order to provide support to people as they became ill in greater and greater numbers.

We have, for example, in San Francisco a program that includes an education component where the major educational efforts regarding the transmission of the disease and protection of the disease are actively pursued throughout the community. A second organization, working in conjunction with the educational programs, has been established to provide support services and some housekeeping services to individuals with aids and their loved ones.

These programs have been very helpful with a disease that is so devastating and in cases where there are so many, many needs for individuals. For instance, buddy programs are particularly useful in terms of providing ongoing support to people who are devastated by their diagnosis and their illness. In addition to that, the hospice programs that have been set up have been providing people with an opportunity to receive many health-care services and support on an outpatient basis in an environment that is much more pleasant and comfortable than many of the health-care environments that we would otherwise find ourselves in.

These types of programs will probably need to be replicated in many of our health-care environments, including the VA environment. We would hope and recommend that the VA and other organizations that will be providing health care services will carefully look at this type of support mechanism in terms of helping patients and maintaining as much cost effectiveness as we can, as we provide for these very, very ill patients.

These organizations have also provided education programs, and I am distressed that we have heard so little about education because I believe the VA system has an excellent opportunity to rapidly enhance the desperate need for education. A recent study that I read indicated that 40 percent of the population does not know how the HIV virus is transmitted. If they think it is from sneezing, we have a serious problem. If they don't know that it is from sex or from other high risk behaviors, we have a serious problem.

As we learn more about the disease, education of the general public is very important. With all of the inpatient and outpatient transactions in the VA system, there is an opportunity for extensive education, which we all must support and become involved in.

I have brought with me today some educational materials that we think are particularly useful, and I will give them to you for part of the record.

The Council is also concerned about testing. We have heard of the terrible discrimination problems which occur and many of the people that we have worked with have had those types of experiences. We do believe that informed consent must include the social ramifications, emotional ramifications of testing prior to individuals making the decision to be tested. We strongly recommend that there be antidiscrimination legislation before we promote a much more extensive testing program.

I hope this information is helpful, and I am available for questioning.

Chairman **CRANSTON**. It is helpful, and I thank you very much. Dr. Schafer?

[The prepared statement of Ms. McFarren appears on p. 177.]
[The educational materials are retained in the committee files.]

STATEMENT OF DR. PAUL W. SCHAFER, EXECUTIVE DIRECTOR, NATIONAL ASSOCIATION OF VA PHYSICIANS

Dr. **SCHAFER**. It is a pleasure to be here to testify this morning. As you know, I am a full-time VA physician, a surgeon, the Chief of Chest Surgery here at the Washington, D.C. VA Medical Center; and I am also the Executive Director of the National Association of VA Physicians, otherwise known as NAVAP. And I speak today in that latter, strictly unofficial capacity.

There has been so much information revealed here in the course of the hearing this morning that I will restrict my remarks to just a part of my testimony, which has been submitted and which I hope you will include in the record.

Chairman **Cranston**. Yes, it will go in the record.

Dr. **Schafer**. The NAVAP Board of Directors has recently reviewed its previously published position on AIDS and that, too, is submitted for the record. We are now more than ever appalled by the words and actions of those would fan the flames of the epidemic of fear and hysteria that could occur about this emotion-charged disease. Though much needs to be learned about the disease, as you know there is no scientific basis for yellow gloves to be worn by police handling street demonstrators or by court bailiffs at arraignment proceedings.

It is hoped that the 1988 elections will not become a field day for some demogogues who would make the yellow glove a campaign symbol. We call on the veterans' service organizations and others to join with us in protest of President Reagan's inclusion of the Nation's veteran patients in his recent remarks about HIV antibody testing of prison inmates and aliens seeking to enter our country.

The agency must not promote policies or actions throughout the system implementing such practices for our patients and the health-care workers who serve them. AIDS is an infectious disease for which the profession has well-established procedures for management of afflicted patients and the workers who do care for them. We strongly urge strict observance of the Centers for Disease Control guidelines concerning precautions that should be taken in dealing with blood or body fluids in which the AIDS virus might be transmitted, precautions that are already taken in dealing with other infectious diseases such as hepatitis B.

Surgical teams practicing aseptic technique to prevent infection of patients are at one and the same time protected from AIDS patients upon whom they operate. Viruses, bacteria, fungi, and parasites opportunistically infect the lungs of immunosuppressed patients. Such life-threatening infections can be very difficult to diagnose. I regularly operate on such patients to obtain lung tissues for biopsies that permit accurate diagnosis, often leading to lifesaving specific treatments.

NAVAP is strongly opposed to compulsory mass screening of VA patients and health–care workers. HIV antibody testing should be performed only when the professional-clinical indications justify that the test should be made, and no such test should be made without specific informed consent.

Much evidence exists that lowering of high-risk behavior results from education and counseling in connection with tests, rather than with the specific results of the testing itself. NAVAP encourages the development of effective educational and counseling procedures as opposed to compulsory testing which will scare away high-risk groups from seeking medical care. Available VA funds should be expended for education, counseling, and research, not mass testing. The testing of all VA patients will cost a very substantial amount.

In summary, the National Association of VA Physicians is opposed to compulsory mass HIV antibody testing. Such tests should specifically and professionally be indicated and should be performed only with specific informed consent. The VA should expend its funds on high quality education, counseling, research, and patient care, and on the confidential testing of those who wish it. The VA should develop an active and aggressive education campaign for all VA employees from physicians to janitors, which should include decreasing risk of exposure and an understanding of the social and psychological consequences of positivity.

Finally, this is no time for hysterical fear. AIDS is a serious problem for American society and its only present hope for containment is education. Fortunately, it still remains a very difficult disease to catch. Thank you, sir.

Chairman **Cranston**. Thank you very much.

[The prepared statement of Dr. Schafer appears on p. 186.]

Chairman **Cranston**. I am going to have very brief questions for each of you. First, Ms. Foley, I think it is very significant that, as the representative of nurses, you have testified against mandatory testing of hospital patients and testing only with informed consent. Can you tell us how you reached that position and the extent to which you have a concensus among your members on this?

Ms. **Foley**. Yes, sir. The decision was reached at our June House of Delegates meeting, but that was the culmination of many of the structural units of the American Nurses' Association and the constituent State nurses' associations deliberating in the last year. There have been three cabinets, our Human Rights Cabinet, our Ethics Cabinet, and the Cabinet on Economic and General Welfare, which have dealt with the issue of workplace policies for AIDS testing and the care of the AIDS patient. And in action on their reports, our Board of Directors did produce a statement in June which was amended by the membership in attendance at the House of Delegates; those members numbered 598 at the time of the vote and are reflective of the members throughout the country.

And I believe it was with a great amount of discussion and education that our membership did come to the conclusion that testing would not provide the security. What in fact really provides security in providing nursing care is just using the prescribed precautions and dealing in advance with the knowledge of what the modes of transmission are. Our main enemy has been fear and misinformation, and we have had some very tremendous educational programs. And I do have a pamphlet to share with the committee from the California Nurses' Association. We have conducted programs throughout the State, some with support of State funding.

Chairman **Cranston**. Was there a broad concensus?

Ms. **Foley**. It was unanimous, sir.

Chairman **Cranston**. It was unanimous?

Ms. **Foley**. Yes, it was. We were very pleased with that. I think it reflects very good decision-making on behalf of nurses, who are the direct care givers.

Chairman **Cranston**. CDC has issued guidelines regarding precautions that the health-care workers should take to avoid exposure to HIV. Do you believe those guidelines are adequate to prevent transmission in health-care settings?

Ms. **Foley**. Yes, we do. We endorsed those guidelines last year and then also endorsed them after the discussion on the invasive procedures. We feel that they do provide adequate protection. We have used them consistently with the hepatitis B; and because of the similarity in the modes of transmission, it is appropriate. I think Dr. Curran's comments about the addition of goggles and masks will probably be additional procedures for invasive procedures or where there is the opportunity for splashing of body fluids.

I myself have changed my own practice habits. I administer blood two or three times a week, and I also take care of a mixed population, somewhat with an elderly population who we would assume would not be at risk but, in fact, because of orthopedic surgery, many of these patients have received blood transfusions, and a few have become infected. I have just changed my behavior, as have most of the people I work with. Those who are educated are still providing excellent care, humane care.

You don't wear gloves when you give your tablets or your back rub, but you do wear gloves when it is body fluid exposure. And we have been able to balance it. I think there will still be some fear, and there will be individuals who are reluctant to care for the patients in the most humane way. I think education will be our greatest opportunity.

Chairman **Cranston**. Thank you very, very much.

Ms. **Foley**. Thank you.

Chairman **Cranston**. Ms. McFarren, I was pleased to hear your call for the VA medical system to initiate a sweeping educational campaign. As you know, I agree completely. What, in essence, do you think should be included in that campaign?

Ms. **McFarren**. It certainly should include information regarding the transmission of the disease and how we can protect ourselves. I think one of the things that is very interesting about people who want testing is they seem to think that, if people are tested, then they are protected from the disease. Health care professionals can protect ourselves by simply using sensible actions as we interact as health-care providers or with individuals infected with the AIDS virus. Specific major pieces of information should go to the general public, enough so that they know whether they might be at risk and need additional information.

Availability of additional information needs to be sensitive to cultural needs and individual's personal needs in order to assure that they understand how the disease is transmitted and what they must do in order to avoid transmitting the disease to someone else or avoid receiving the disease from someplace else or someone else.

Chairman **Cranston**. Do you believe, in order to develop the most effective materials, the VA could benefit by having input from community-based organizations that have been developing such educational campaigns?

Ms. **McFarren**. Absolutely. As a matter of fact, I suspect that they would be off target if we did not use those types of groups 'experience in order to expand and use our program.

Chairman **Cranston**. Dr. Gronvall, if you could consult with such groups as you develop your educational campaign, I think that would be helpful.

Dr. **Gronvall**. Yes, we certainly will.

Chairman **Cranston**. Good. Dr. Myers, in your prepared testimony, you do not mention two concerns which others often cite as reasons for giving the individual the right to informed voluntary consent to testing: first, the psychological impact of learning that one is infected; and second, the notion that involuntary testing may be counterproductive to the effort to obtain the individual's voluntary cooperation in modifying his or her behavior. What weight do you give to those factors?

Dr. **Myers**. I think they are both important, but I would not give them undue weight. I think that testing is clearly something that we must pursue much more vigorously than it has been pursued in the past and that we must, as health-care providers, help to convince our patients that it is important for their personal health and the health of the ones who are around them to get tested.

Now, I think it becomes, Senator, more a matter of how you go about doing it. If you provide a written form for patients where they are forced to read a number of technical paragraphs or that is full of jargon that basically can scare them away, then that is a different situation than sitting down with them and telling them that it is important for their health and that there are some potential risks; and then encouraging them to have the test. So, I am much more in favor of having that personal interaction and much less in favor of having specific documented informed consent forms for the seropositivity test.

Chairman **Cranston**. Thank you very much. Dr. Schafer, I thank you for your very constructive testimony. Do you believe that the confidentiality of medical records that currently exist in the VA system is sufficient to safeguard the protection of test results of the HIV antibody test, especially if testing became widespread and mandatory?

Dr. **Schafer**. I share with Dr. Gronvall this very, real concern; and I am afraid my answer to your question is that I don't believe it is adequate, and I am not exactly certain how it can be made adequate. The medical record obviously contains all sorts of privileged information that should not be treated without full sense of the importance of confidentiality; but the fact is that an awful lot of people see those medical records inside the VA hospital.

We don't have them chained and locked up in a secure fashion. This is a very dynamic, health delivery setting in which many people would have opportunity to see such information if they were curious enough and energetic enough to want to do it. But beyond that, once the record is brought together inside one of our medical administrative services, the fact is that the record is still retrievable under many settings.

Dr. Gronvall mentioned the one that is so very obvious and is a matter of great concern, and that is that it can be retrieved by insurance companies in respect to authorized third-party payment. So, I am concerned about it, and I really don't think that it is as confidential as it should be.

Chairman **Cranston**. If you can develop any recommendations for us as to how to make it more secure, we would certainly like to have them. If you could submit your thoughts in writing on that, it would be helpful.

Dr. **Schafer**. We will be glad to do that.

[Subsequently, Dr. Schafer furnished the following information:]

It is our intention to explore the possibility that the Agency's Decentralized Hospital Computer Program (DHCP) can be programmed for secure treatment of HIV antibody test results.

Chairman **Cranston**. Under what circumstances would you encourage a patient to have the test done?

Dr. **Schafer**. I mentioned in my oral testimony that there certainly are well-established professional-clinical indications for one to want to know about HIV positivity. Of course, all of those circumstances would be occasions when one would want to talk with the patient and convince him/her of the importance that this has in respect to their and our understanding of their disease and the potential for treating them and treating them correctly.

Now, as you get to the less clear circumstance of wanting to know about HIV antibody positivity in a nonclinical and nonprofessional indicated setting, I don't have good and clear answers to present to you about that. As you noted in my prepared testimony, I am very much concerned about all of the adversities that would attend mass screening; and among those, of course, is the horrendous problem posed by false positivity.

Chairman **Cranston**. I thank each of you very much for being with us. I thank you again particularly for coming all the way across the country. Thank you very much.

Now, we will go to our final panel of Veterans' Administration field staff, consisting of Dr. W.A. Crow III, Houston, Texas, Associate Chief of Staff for Ambulatory Services, Houston VA Medical Center; Dr. Earl Gordon, Los Angeles, California, Chief of Staff of West Los Angeles VA Medical Center; and Dr. Michael Simberkoff, New York City, Chief, Infectious Disease Section, New York City VA Medical Center.

I thank each of you for traveling to be with us this morning. Dr. Gordon, I particularly thank you for coming so far, as I thanked one of the previous witnesses.

Dr. **Gordon**. Thank you.

Chairman **Cranston**. We have invited you here because your medical centers have among the heaviest AIDS caseloads in the VA. In fact, Manhattan and West Los Angeles are the two highest caseloads in the VA. We have a number of questions for you. Unfortunately, I have to leave in just a couple of minutes. So, I will not be able to complete all of them.

I am going to another matter connected with VA medical care. So, our Chief Counsel, Jonathan Steinberg, seated at my left, will pose most of the questions to you. I do want to pose one question before I leave.

What are your personal and professional views on the proposal we have been discussing all morning to test all inpatients for the HIV antibody? Will each of you give a very brief answer? It has to be done in about 2 minutes because I have to leave that fast.

Dr. **Crow**. Senator, I think it has been clear, and I have the opinion as well that routine testing on all VA inpatient admissions is not indicated scientifically, nor do I think it is possible, given our present resources.

I think we need to focus our testing. I think we can focus that testing, and I think routine testing of those focused groups may well be indicated. Those groups could be males between the ages of 20 and 40; maybe they are all presurgical patients, or certainly all patients in identified risk groups. I don't want to comment specifically on what those focus groups would be, only to say that I think that is where our efforts should be—to determine what those focus groups are and move on.

Chairman **Cranston**. Thank you. Dr. Gordon.

Dr. **Gordon**. I, too, Mr. Chairman, would be opposed to mandatory testing. My first concern is that it would keep veteran patients from seeking care in our medical centers, and I don't want to deprive any veteran of the care to which he is entitled. Second, it deprives patients of their right to participate in decisions relative to their health-care delivery. There are other reasons, too, but I think these are the two essential ones that govern my decision.

Chairman **Cranston**. Thank you very much. Dr. Simberkoff?

Dr. **Simberkoff**. Senator, I am also opposed to routine testing. My major concern is the importance of counseling of patients. I think that counseling must be begun before the test is done, and the counseling can start in the process of acquiring the informed consent, which I think is necessary for any test to be successful. I think we must have pre-test counseling, testing, and then post-test counseling, then open our doors—which is the key to dealing with patients if they are positive—tell them that they have a place to come for medical care and evaluation. Then, we will have a successful program for dealing with HIV; and without those, we will not.

Chairman **Cranston**. Thank you very much. I thank each and all of you, the witnesses at the table now and others, for their participation in this very productive hearing. Jon Steinberg will now carry on. Thank you very much.

Mr. **Steinberg**. Perhaps if we could backtrack a moment, it would be helpful for the purposes of the record. If each of you, starting with Dr. Crow, would identify your responsibilities in connection with AIDS patients at your medical centers? Dr. Crow?

Dr. **Crow**. I am Associate Chief of Staff for Ambulatory Care in Houston. I have a broad range of activities in that role. However, my role with HIV infected people springs primarily from my position as a staff internist in the Internal Medicine Service in Houston.

I started our AIDS screening program back in 1982 and have been very active in close, hands-on care delivery to these patients.

Mr. **Steinberg**. Dr. Gordon.

Dr. **Gordon**. As Chief of Staff of the Wadsworth Division at VA West Los Angeles, I of course have primary responsibility for the quality of care delivered to our patients and also the responsibility to carry out VA regulations in this regard.

Mr. **Steinberg**. Dr. Simberkoff?

Dr. **Simberkoff.** I am the Chief of the Infectious Diseases Section at the New York VA. Our facility has seen 340 AIDS patients since 1979. That represents about 1 percent of the AIDS cases that have been reported in the United States and about 17 percent of all the cases reported in the VA system.

As Chief of the Infectious Diseases Section, I oversee the care of these patients from the point of view of their infectious problems. All of the patients are referred to the Infectious Disease Clinic following discharge from the hospital, so that all of the individuals with AIDS and all of the individuals known to be HIV positive or to have symptoms suggestive of ARC are also followed in our clinic.

Therefore, the clinical care in and out of the hospital largely falls under my supervision. In addition, I have been involved with clinical research in these areas. I am a co-chairman of the VA Cooperative Study Program, which you have heard described as a program which is supported by the VA Medical Research Department, the VA Cooperative Studies Program, and the Department of Defense. It is a trial which is being conducted of the efficacy of AZT in patients who have AIDS-related complex; and it is currently being carried out in New York, Miami, Houston, West Los Angeles, and San Francisco.

Mr. **Steinberg.** I wonder if each of you could tell us—and we will start with you, Dr. Simberkoff—what policy is followed at each of your medical centers with regard to HIV testing, from the point of pre-test counseling, informed consent, post-test counseling, et cetera?

Dr. **Simberkoff.** Yes. Our hospital has had a policy which required a written informed consent for HIV testing since that test became available in 1985.

Mr. **Steinberg.** Could I interrupt you for one second? Would you please provide us a copy of that informed consent form?

Dr. **Simberkoff.** Yes.

Mr. **Steinberg.** Thank you.

[The consent form appears on p. 190.]

Dr. **Simberkoff.** The consent form describes the test itself, tells the patient its significance in terms of progression to AIDS is not known, that the patient will require further followup if the test is positive, and that the Infectious Disease Clinic will provide that followup for him. And it also informs the patient that the results of the test will be included in his medical record; that the medical record is available to other hospital personnel, but is otherwise considered a confidential hospital document.

We share some of the concerns that have been expressed earlier by Dr. Gronvall and Dr. Schafer about the way those charts are sometimes used. Nonetheless, all of our patients are aware that the results of the tests will be put on the chart if they are positive.

Mr. **Steinberg.** I don't think you covered the pre-test counseling.

Dr. **Simberkoff.** Oh, I am sorry. Counseling is actually begun at the time that the patient is first approached concerning the performance of the test. We explain to the individual, first of all, the nature of the test and also we will discuss the HIV infection itself—the means by which it is transmitted, the possible manifestations of the disease, and that further transmission of the disease may be prevented. Once the test result is available, the patient is again brought in for a personal contact with a physician or an AIDS specialist nurse to discuss the results of the test. The results are not given over the telephone.

Again, we review information about the test itself and its significance, inform the patient that they can be followed in our clinic and should be followed in our clinic if the results are positive, and further counsel them about transmission of the disease and means to prevent further spread of it through sexual encounters or through sharing of blood or donating blood for transfusion.

Mr. **STEINBERG**. What do you tell them if they are negative?

Dr. **SIMBERKOFF**. Individuals who have negative tests usually are ecstatic when those results are given to them. We tell them that the result of the test does not mean that they may not become positive at some time in the future, and we then counsel them about ways that they may acquire infection through multiple sexual contacts or sharing of blood or needles through intravenous drug abuse.

Mr. **STEINBERG**. Do you tell them indeed that the negative result doesn't indicate that they are not then positive?

Dr. **SIMBERKOFF**. We tell them that the test indicates that there is no evidence of infection that we can detect at that time. Most of these individuals have come to us as a result of past histories of high-risk behavior, either homosexual contacts or intravenous drug abuse. We stress to them that there is a very low but present number of false negative tests, for which we cannot entirely exclude the possibility of the virus being present. We also stress to them the fact that the high-risk behavior which they may have practiced in the past will certainly put them at risk of acquiring infection, should they continue such behavior.

Mr. **STEINBERG**. The point is made clear that, just because they have a negative test result, it does not mean they can resume their high-risk behavior?

Dr. **SIMBERKOFF**. Exactly.

Mr. **STEINBERG**. Indeed, if they do, they need to be tested again?

Dr. **SIMBERKOFF**. Exactly.

Mr. **STEINBERG**. Dr. Gordon.

Dr. **GORDON**. First of all, we limit our HIV testing to those in which there is a clinical indication or suspicion of AIDS related complex or AIDS, although I would hope that we could extend this on a voluntary basis to other members of high-risk groups. We ask our physicians to do a pre-test counseling, as has been previously indicated by Dr. Simberkoff.

And then, we require a written and signed informed consent on every patient.

Mr. **STEINBERG**. Would you please share a copy of that with the committee?

Dr. **GORDON**. Yes, I would be happy to.

[The consent form appears on p. 194.]

Mr. **STEINBERG**. Thank you.

Dr. GORDON. This signed informed consent goes with the blood specimen to our clinical laboratory. No specimen is sent out to Lexington or to commercial laboratories without the presence of that signed consent in the laboratory.

The specimens are then sent out by code to either Lexington or a commercial laboratory, and we maintain rather strict confidentiality of all test results, which are retained by our chief of our laboratory service. The results are then reported directly—verbally—by the chief of the laboratory service to the primary physician, be the result negative or positive; and then the patient is called in to discuss the results with a physician and counseled. And this, of course, is the most important part of the counseling.

We also ask our physicians that notations of counseling and blood test drawing be recorded in all of the medical records, although at the present time we have kept the printed test results out of our laboratory computer system and out of our medical records.

Mr. STEINBERG. So, at West Los Angeles, the result, positive or negative, of the test is not entered into the medical record?

Dr. GORDON. It has not been up to this time. First of all, as you know, the laws of the State of California, which we try to recognize, enforce strict confidentiality. Second, with our four main clinical units scattered over a large geographical area, I feel uncomfortable about the confidentiality that we would achieve if the tests were put in the medical record at this point in time.

Mr. STEINBERG. Now, if the patient is symptomatic, that is a different matter with respect to what goes into the medical record. Is that correct?

Dr. GORDON. That is correct. The diagnosis of AIDS or AIDS-related complex is plainly documented in the medical record, and this is known to everyone; and certainly, confidentiality at that point is not that important for this group of patients. I must say that our informed consent does permit us to put in the medical record the results of their tests in every case.

Mr. STEINBERG. But if I understand you correctly, the policy is that those test results remain in the laboratory in a central repository?

Dr. GORDON. A locked repository, with access by any health-care provider who has a need to know.

Mr. STEINBERG. Dr. Crow.

Dr. CROW. At Houston, we likewise have an informed consent procedure. We developed that informed consent form in accordance with hospital policy, under which we have been operating now for 2 years, since this test was available.

Let me give you first our old policy and then the new policy that is currently under revision and will probably be approved. In the beginning, we offered the HIV antibody test only to individuals who had a symptom complex that would make the diagnosis of HIV-related disease a likable one, patients identified in high-risk groups.

We would not allow that test to be ordered except over the signature of a staff physician in the Infectious Disease Service or in the General Medicine Service who had some experience in dealing with this disease. The patient was asked to sign an informed consent that specifically related to the patient what he could expect to get from the results of this test, what he couldn't expect to get, what it meant, what it didn't mean, et cetera.

About the first of this year, we realized that the policy was cumbersome. So, we have liberalized that policy now to where the test can be ordered by any staff physician or any staff dentist. We make a very concentrated effort in accordance with CDC guidelines to offer that test to all patients that we identify to be in a known risk group. We offer the test to them, whether they ask for it or not. Obviously, we still utilize the test in the areas where it is clinically indicated, based on the symptom complex. The consent form has remained essentially the same.

Mr. STEINBERG. Will you please provide us with a copy of that form?

Dr. CROW. Yes, I will.

[A copy of the consent form was not available at time of publication.]

Dr. CROW. On the back of the consent form, much like Dr. Simberkoff describes, is a statement whereby the referring physician will readily know to whom he can refer his patient for information if he is not prepared to give that information; and likewise, a specific set of points fashioned after the CDC guidelines and other relevant counseling aspects on a patient who is HIV positive or negative. I think it is inherent in the informed consent process that the patient does get pre-test counseling.

Post-test counseling is carried out by face-to-face contacts. Once again, we don't give results over the phone. Our patients are called in, and they are counseled at that moment, whether they are positive or negative. We make a very strong effort, once again, in high-risk group populations to make them understand that this test is not the be-all and end-all; it means at this point in time there is no detectable evidence of exposure to this virus. But that is all it means.

Mr. STEINBERG. Tony, I have several other questions, but after one more, I will yield to you and then come back.

I might make a comment. It has always been somewhat of a mystery to the committee why, in an instance like this, a system, which is to some extent a centralized medical program, has three informed consent forms that have been developed independently. I am sure each of them is very good and has its own strengths and perhaps weaknesses. Why doesn't the Central Office in a situation like this, provide to medical centers—if not a standard form that each center should use, if it wishes to—a sample form for guidance that medical centers might wish to adapt to their own uses? I am actually addressing this observation to some extent to Dr. Gronvall, Dr. Cohn, and Mr. Lindsey, who are still with us, and I would ask them to give some consideration to that.

But I wonder if any of you would like to comment on that? Dr. Simberkoff?

Dr. SIMBERKOFF. I would just like to make one comment. There is a VA Infectious Disease Advisory Group which met to discuss the issue of AIDS in the VA a couple of years ago. At that time, several of us—including I think representatives from West Los Angeles and several other hospitals—talked about policies that were currently in practice for testing for HIV at the respective medical centers.

And we did distribute, at least among ourselves, copies of the informed consent forms that were being used at that time. I believe that these have been made available to other medical centers upon request, and I think that in some cases they have been either copied or modified appropriately for the purposes of the local hospital.

Mr. **Steinberg**. I think what you are commenting on is this so-called underground railroad, which has always worked.

Dr. **Simberkoff**. Yes.

Mr. **Steinberg**. I guess I am wondering why we can't use the overground route more often. Dr. Gordon.

Dr. **Gordon**. It is my understanding that VA policy does not require a written informed consent.

Mr. **Steinberg**. Yes, I believe that is correct.

Dr. **Gordon**. They do require that a written informed consent be a part of every medical record. It doesn't have to be a form.

Mr. **Steinberg**. Right, and I believe also the current policy is that a notation that informed consent was in fact given should appear in the medical record.

Dr. **Gordon**. In the medical record; that is correct. However, when you tell physicians—and we have a number of residents that rotate through our hospital—you hope that everyone will counsel every patient. I feel that at least we have developed a form that, if the counseling in any way is inadequate, at least I feel safe that the patient has been given a certain basic amount of information. And this is why we developed our own forms, to meet our own needs at a given facility; and we appreciate this flexibility.

Mr. **Steinberg**. I guess what I would suggest at a minimum—and I noticed that each of you from the field are not calling for Central Office direction—that, without respect to whether or not the Central Office should require a consent form—it does not, as you say at present—it would be appropriate if the Central Office said here is a form that has been adapted from the experience of our medical centers with the largest populations of AIDS patients. Or maybe here are three different forms, and we send them to you in the event that you wish to use them.

It would seem to me that a centralized medical system could at least anticipate the needs of its medical centers and provide that kind of guidance and assistance. Dr. Gronvall has been kind enough to remain with us and also to join us, and he certainly deserves equal time on this issue.

Dr. **Gronvall**. I don't know if Dr. Cohn might want to comment first.

Mr. **Steinberg**. Dr. Cohn, did you want to comment first?

Dr. **Cohn**. Yes, just one thought. The piece of paper, in our minds, is not near as important as the concept for which it stands. I think this point was brought home as late as last week in the conference mentioned earlier in the testimony. It is a concept of informed consent, I think, that makes the difference; and I think guidelines from Central Office have been fairly specific along those lines, that informed consent will be obtained.

The form itself—the piece of paper—I think is individual, and quite frankly, in my mind does not carry near the weight, if you will, that the concept does.

Mr. **Steinberg**. Dr. Gronvall.

Dr. **Gronvall**. If I may, Mr. Steinberg, I should comment that I have had little preparation to respond to criticism that we have provided inadequate amounts of guidance, forms, rules, or requirements to our medical centers. So, as a generalization, I hardly know how to respond to that criticism since it is almost never made.

If I could be serious, I think the comments have been right on target. We have deliberated extensively exactly on that issue, came to the conclusion that there was not either a need for or a requirement for a written consent form to do AIDS testing. I think we have distributed to the field documents that describe again and reinforce the importance of gaining informed consent, and I agree totally with the description that it is the exchange of information and understanding between the physician and the patient that counts in gaining the patient's understanding of what is going on and pre- and post-test counseling is what is critical.

So, we have reinforced the need for informed consent, but wanted to stop short of either prescribing or even really strongly urging the development of a written form. It is clear that information circulates around among our hospitals through the underground railroad and through other informal means and the General Counsel's Office——

Mr. **Steinberg**. And through congressional hearings.

Dr. **Gronvall**. Yes. And the General Counsel's Office has been well aware of this and involved in it; and the fact that some of our individual medical centers have chosen—based on their own unique experience—to develop a written form that helps them achieve informed consent with their patients is something that we view as an appropriate local exercise. I have reviewed the specific forms, in fact, that are being described; and in each, there is additional information that is really unique to that individual institution or to the fact that research studies are going on. and so there is an explanation of the use of this information in a research center setting. That kind of information wouldn't be utilizable across the entire system.

So, I really support the local initiative in this case to develop a form, if that is desired, that is unique to the individual institution and the setting and the patient characteristics, rather than imposition of a form. You didn't call for us to impose a form; so perhaps I am overreacting to the question. So, the only thing additional I would say is that we view our role in the Central Office as providing guidance on the characteristic of informed consent and then leave the local medical staff to work out the best way to accomplish that, that is unique to the individual setting.

Mr. **Steinberg**. As I said, it seems as though each of the local facilities represented here is perfectly comfortable and happy with that degree of discretion. So, I will exercise a lot of restraint and won't pursue this. Tony?

Dr. **Gronvall**. Thank you very much. [Laughter.]

Mr. **Principi**. Thank you, Jonathan, and thank you, gentlemen. I just have a very few questions. Dr. Gronvall's testimony indicates that there is a rather wide disparity in the funding provided to your institutions under the resource allocation methodology. You receive somewhere around $8,000, for the treatment of an AIDS patient when the actual cost of such treatment, with figures ranging anywhere from $24,000 to $38,000. Given the relatively high percentage of AIDS patients in your facilities, how do you deal with that shortfall? Dr. Simberkoff.

Dr. **Simberkoff**. It has been a very difficult problem for the center, and some of the information that Dr. Gronvall alluded to has been developed by each of the participating centers here today. So, I think each of us have had to deal with this problem. Obviously, we are interested in developing better methods for caring for our patients, as well as being reimbursed for them. I think that we all feel—or certainly we in Manhattan feel—that we are reaching a crisis stage in terms of our personnel and facilities available for dealing with the increasing number of patients who are currently recognized as having AIDS or being followed in a hospital or a clinic, those who are being recognized as having AIDS-related complex and perhaps are progressing to AIDS at a greater or not so great rate, and those individuals who are HIV positive but with minimum immunological dysfunction who need to be followed but at less frequent intervals.

We certainly are trying to develop strategies and individuals in the Central Office have been very helpful in assisting us in this—in developing better means of treating these patients in the hospital, out of the hospital in day care centers, and in clinics. And we are hopeful we can develop a unit concept which will improve our ability to treat these patients on an ongoing basis.

Mr. **Principi**. Dr. Gordon, how does it impact on your facility, and does it impact on the non-AIDS population of the facility? By that I mean the fact that you have to reduce your level of services facility-wide.

Dr. **Gordon**. No, we do not reduce the care of other patients. We just manage to get by. And I will tell you that the recent allocation of funding that we received from VA Central Office will be of tremendous help to us, and I think will adequately get us through this fiscal year. It would be very nice, since the resource allocation methodology does not provide us sufficient reimbursement, if we could have funding that we could predict with regularity on an annual basis and, hopefully, maybe the VA budget will permit this in the years to come. From this point forward, I envision a much more serious problem. While I think $20,000 to $25,000 per case is a reasonable approximation of what we would spend, this figure was derived before AZT was implemented.

We just started offering AZT to our patients about 3 months ago, and already we have 22 patients on AZT. These are outside of our cooperative studies. And at the present time, the cost of AZT to our pharmacy, is $8,000 per patient per year, if the patient lives and has the AZT for a full year. And we are going to see more and more of these patients who may qualify for AZT. So, really, you have to now add another $8,000 onto the basic cost of medical care for these patients.

Mr. Principi. Thank you, Doctor. Doctor Crow.

Dr. Crow. I think the cost of these patients has impacted us in Houston in two primary ways. One is pharmacy cost, and I am not speaking specifically about AZT—certainly that is a major component—but just the cost of the other antimicrobials that these patients often require. So, pharmacy costs will certainly, I think, eat up most of that extra allocation that we recently received, without which I think we would have a very difficult time.

The second area of major impact is the laboratory cost. We recently looked at a series of 20 or so of our AIDS patients in the last fiscal year and found out that we used five times the number of laboratory procedures in the care of these patients than we would in a regular non-AIDS patient.

And a lot of time that laboratory cost is not the routine, cheap CBCs or serum chemistries. It is the more sophisticated viral cultures and other things along those lines. So, it is a very difficult area for us to compensate for the load.

There are movements under way, of which I am aware, in the Central Office to perhaps make the resource allocation methodology a little bit more responsive, you know, to this problem, especially one that is increasing logarithmically, if you will, in incidence.

Mr. Principi. Thank you. Dr. Gronvall.

Dr. Gronvall. If I may, I appreciate the excellent comments that have been made. We have in fact taken steps to try to come to grips with this issue for the 1988 budget on a regular basis so that we won't be in the position of having to make a special allocation part way through the year.

We have created a task force that is, in fact, chaired by the Director of our Manhattan Hospital because we felt—as Dr. Simberkoff pointed out—that they have had the greatest amount of experience and, in fact, much of our cost information has come from their experience. So, we created the task force, chaired by Mr. Garfunkel, the Director of the Manhattan VA, with other appropriate people; charged them to develop a recommendation, which I expect to receive by mid-July, that will recommend how our initial budget allocation to each medical center for the fiscal year 1988 year, which will start October 1, 1987, can take into account the best informed projection that we have of what the caseload of AIDS patients will be and what the cost of that care will be during 1988, so that we build that into the medical center's budget at the beginning of the year.

Once again, however, although we will do that, we have all testified that it is very hard to predict the future; and unanticipated changes either in the incidence of the disease, the caseload of the disease, or the availability of treatments—which may in themselves be very expensive and increase the cost—those may change during the course of the year. So, I think this is a situation that requires continual monitoring; and that is really why, during this year and last year, we made a special additional allocation to the high-incidence hospitals part way through the year.

While I hope we don't have to do that next year, if there is some change, we will do it again because our goal is to ensure that each of the medical centers with a substantial incidence of AIDS cases has the resources necessary to provide excellent care to those veteran patients.

Mr **Principi**. Is the cost of AZT coming down, Dr. Gronvall?

Dr. **Gronvall**. I assume that it will as manufacture expands. The drugs have been in very short supply. Back at the time that we got approval to do the controlled study that we have described, the drug was in such short supply that there was question about whether the study could even be mounted. We gained approval, and that really represented, I think, a national decision that this controlled study done in the VA was so critical to this disease that a certain amount of that drug should be allocated for this study.

We are doing the only study of that sort because the drug is in short supply. I have been told recently that other manufacturers are moving into the area and that—and I have forgotten which pharmaceutical manufacturer produces AZT—but the production is being expanded. And I would assume, as is usually the case, that with expanded production, the cost will come down; but I don't think we have seen it yet.

Mr. **Principi**. One further question, John, please?

Mr. **Steinberg**. John, why don't you just remain there for a few moments, if that is all right?

Dr. **Gronvall**. It is fine with me. I am not a witness.

Mr. **Steinberg**. It is fine with the committee.

Dr. **Gronvall**. I will be pleased to answer.

Mr. **Principi**. Could you tell me what is your current AIDS population—diagnosed AIDS population? And perhaps more importantly, what would be your estimates of the number of veterans who are being treated in your facilities for ailments from pneumonia to lymphoma which may be interwoven with AIDS but there has been no diagnosis for the specific HIV or the AIDS? Any ideas along those lines?

Dr. **Simberkoff**. Yes. As you probably know, the criteria for the diagnosis of AIDS are quite strict. We use the criteria which are established by the Centers for Disease Control, and they are themselves in the process of being revised. Copies of the revised criteria have been circulated and were circulated at the Third International Conference. They will probably be formally adopted within the next few months. So, some of the patients that we currently call AIDS-related complex may be reclassified as AIDS, once those criteria are adopted.

We are currently aware of—our total number of AIDS patients is, as I said, 346. Of that group, approximately 200 have died, give or take a couple. So, about 130 to 140 are alive and are being followed in our facilities and clinics. Of that group, 90 percent were diagnosed initially at our hospital. Ten percent came to us from other facilities, some private facilities in the New York City area where patients exhausted their medical insurance and came to the VA only after they were forced to do so because of economic reasons. Some individuals came to us directly from the military service, after being discharged with diagnoses of AIDS. So, that represents about 10 percent of the patient population. In terms of the number of individuals with AIDS-related complex that we are currently following, it is somewhere between 50 and 70 patients. The limit to the number of patients that we can follow is simply the limit of the size of our clinic. They are other individuals who are being followed in medical clinics of whom we are aware, but are not following them. They are being followed by medical residents, and they have diseases which are perhaps thought to be related to HIV; but because diagnosis of AIDS has not been made, they are not yet being followed in our clinic.

Mr. PRINCIPI. Would your treatment methodology change if you knew they were infected with the AIDS virus?

Dr. SIMBERKOFF. At this point, no, becauce the only treatments that are available for individuals are treatments with AZT or treatments with a specific infection that is a consequence of AIDS and for which we already are using established therapies.

Mr. PRINCIPI. It would just be the AZT then?

Dr. SIMBERKOFF. Right. All patients who are thought to be candidates for AZT and who wish to be evaluated for that are screened and followed by our clinic. This is one of the legitimate indications for HIV testing and for determination of immunological status. So, if a person wishes to be considered for AZT, either through the VA cooperative study or through open protocols, then he will be referred to the Infectious Disease Clinic. He will have HIV testing and immunological testing done to determine whether he is eligible for one of these treatment options.

Mr. PRINCIPI. Thank you. Dr. Gordon. Dr. Crow.

Dr. GORDON. Since 1980, we have made a diagnosis of AIDS in 174 patients, an additional 24 AIDS-related complex. At the present time, we will have about 10 AIDS patients or AIDS-related complex patients in the hospital at all times. This contrasts with our experience of about four patients a year ago. We have an AIDS clinic in which we are currently following about 75 patients with AIDS and AIDS-related complex. This last week, I appointed an AIDS coordinator for our hospital, and my next step is to coordinate all AIDS patients into a single, dedicated clinic with a multidisciplinary team approach that I think will enable us to give much better care to these patients in that sort of setting.

Mr. PRINCIPI. Dr. Crow.

Dr. CROW. We have had around 100 cases of AIDS that we have diagnosed in Houston since the onset. That number may be a few more or a few less, depending on exactly which statistics one looks at; that is a fairly round number. We have had 32 new cases since the beginning of this fiscal year. I believe for fiscal year 1986, we had 61 unique social security numbers with AIDS in our patient population.

We are projecting around 120 new for fiscal year 1988 and 1989. One statistic which was surprising to me was that in Harris County, or the metropolitan area of Houston, approximately 1,100 cases of AIDS have been diagnosed since the onset of this disease. We have diagnosed 100 of those; I think to take care of 10 percent of the AIDS population in our metropolitan district is fairly surprising.

We have made an effort in the last 6 months to go back and call back every HIV antibody positive patient that we have had in an effort to try to see where they are. That clinic now is approaching 150, I believe, to 200 patients that are actively being followed.

Mr. PRINCIPI. Thank you. Thank you, Jonathan.

Mr. **Steinberg**. Dr. Gordon and Dr. Simberkoff, do you call back positive test patients as well? Do you have any policies on that, as Dr. Crow just mentioned?

Dr. **Gordon**. We would like to have every patient come back to be told personally the results of their test.

Mr. **Steinberg**. I think that he was talking about follow-up beyond that.

Dr. **Crow**. Yes. What I was actually referring to is patients who, since June 1985 when we started doing this test, have been antibody positive, and who may or may not have been referred to our clinic. We have made an effort to go back and call those people back in, whether they were actively in the health-care system or not.

Mr. **Steinberg**. That is what I am referring to.

Dr. **Gordon**. At the present time, we have had limited staffing in our infection control program due to problems in recruitment of nurses; but this is my goal, and this is why we have appointed an AIDS coordinator because I don't want any patients to slip between the cracks. If they don't come back for their appointments, I want to followup on their status. This is our objective, and I think we will be able to achieve it.

Mr. **Steinberg**. Dr. Simberkoff, do you have any comment on that?

Dr. **Simberkoff**. Yes. We do attempt to follow all the individuals; again, not everybody returns for an appointment, but we have a very active secretary who attempts to contact those individuals who don't come back for their clinic appointments.

One point that I would like to add. We talked about HIV positivity as being important as information for the patient. In addition, I think it is important to stress that the immunological tests are very important as monitors of their status, and we attempt to repeat these at regular intervals as well, specifically doing T-4 counts, or CD-4 counts, to determine whether or not the immunological status is deteriorating, informing the patient that these may in some way be related to the risk of the occurrence of opportunistic infections. And also, we inform them that they may be eligible for participation in treatment trials, specifically the VA Cooperative Study and/or the open treatment with the AZT. So, patients have become aware of the importance of following these immunological parameters as well as having clinical followup; and this has encouraged them to return to our clinic.

Mr. **Steinberg**. Dr. Gronvall, let me just make a comment. I assume that the new task force that you describe, in terms of looking at the 1988 allocations, will obviously be focusing on the AZT costs, which could not have been fully considered in the 1987 allocations. Is that a fair assumption?

Dr. **Gronvall**. I don't know that it will focus on that, but that is part of the deliberation.

Mr. **Steinberg**. That will be part of it?

Dr. **Gronvall**. Yes.

Mr. **Steinberg**. That will be clearly part of it?

Dr. **Gronvall**. Yes, it will.

Mr. **Steinberg**. I might indicate to our three field witnesses that a concern about these reimbursements for 1987 and 1988 was strongly held by the committee, both the majority and the minority; and we were very pleased that the VA did make a commitment as to 1988 that the adjustments—to the extent that they could project them—would be made at the outset of the fiscal year rather than, as was the case this year, 9 months into the fiscal year.

Of course, we can't anticipate the future entirely, but we think that is real progress; and we appreciate Dr. Gronvall's cooperation in moving to that result.

Do each of you have drug treatment programs at your medical centers? I know that Manhattan does.

Dr. SIMBERKOFF. Yes.

Mr. STEINBERG. You do?

Dr. GORDON. And we do, too.

Mr. STEINBERG. I certainly knew that. What efforts do you make to encourage patients in the drug treatment programs to be voluntarily tested? I know that Dr. Crow, for example, indicated that the test was offered to them. I am asking about encouraging them to be tested because they are obviously potentially in a high-risk group.

Dr. CROW. Maybe I could respond to that, at least to begin. We have both an inpatient drug treatment program and an outpatient drug treatment program that is primarily methadone maintenance. In both centers, the involved physicians—the supervisory physicians—are very interested in this problem and have made a concentrated effort. I can't give you numbers, but I do know that the effort is certainly there. The effort has been intensified recently in our outpatient drug treatment center in that the involved staff have put together a research protocol in an effort to test not only the patients but also their steady sex partners or spouses along those lines. And I think that will give us a lot of information from that standpoint.

We do make an effort, but I can't give you numbers as to who gets it, how many get it, or how many refuse, et cetera.

Mr. STEINBERG. Dr. Gordon.

Dr. GORDON. I don't know how aggressive our staff has been in that area, but certainly I strongly feel—as I have indicated before—that this group should be offered and encouraged for voluntary testing.

Mr. STEINBERG. Would you try to determine how much encouragement they are giving; and if they are not giving enough, would you perhaps suggest that they give more? And would you advise us of the results of your looking at that, please?

Dr. GORDON. Yes, I will.

Mr. STEINBERG. Dr. Simberkoff.

Dr. SIMBERKOFF. I think that a program to strongly encourage the testing of all risk groups of individuals who are entering drug treatment programs or being seen in the emergency room or clinics of the hospital or admitted to the hospital is really just now beginning to be formulated in an effective fashion.

Mr. STEINBERG. Are you talking about at your facility?

Dr. SIMBERKOFF. At the facility. Up to now, the test has been offered really only on a sporadic basis for individuals, usually after the house staff or one of the attending physicians has recommended that a patient should be tested and approached that individual for the test.

But we are now beginning to emphasize an educational program and a testing program on a much more widespread basis; and we hope to see some fruits of that in the very near future. The facilities for this obviously need to be put in place.

Mr. **Steinberg**. But each of you agrees with the policy of encouraging voluntary testing for high-risk groups?

Dr. **Simberkoff**. Right.

Mr. **Steinberg**. Is that correct?

Dr. **Gordon**. Absolutely.

Dr. **Crow**. Yes.

Mr. **Steinberg**. And would you say that it is your opinion that that is Central Office DM&S policy at this point, as has been communicated to you?

Dr. **Simberkoff**. Yes.

Mr. **Steinberg**. That encouragement?

Dr. **Crow**. Yes.

Mr. **Steinberg**. But that, in essence, it is a program that is just getting started at this point?

Dr. **Simberkoff**. Yes.

Mr. **Steinberg**. Dr. Crow seems to perhaps be the furthest along in that regard.

Dr. **Crow**. I don't know whether that is a compliment or not; but at any rate, we have been actively trying to get these folks, those in recognized risk groups. As I said, it is actually a part of our hospital policy that was written 2 years ago, stating that these are the groups that should be tested, and they should be offered the test.

Mr. **Steinberg**. Dr. Gronvall, is it correct to say that that is Central Office policy that medical centers should encourage high-risk groups to be voluntarily tested?

Dr. **Gronvall**. I believe the answer to that is yes. I don't know of my own knowledge that we have issued a statement specifically in that regard. Earlier, there was discussion about the review that has been going on in the VA about the issue of testing and how it could be expanded. And there was discussion of a document that we had developed that describes a proposal for significant expansion of testing in the VA, and that issue is at the heart of it to identify those veterans who come to us for care who are in programs such as drug testing where they have a higher risk of being infected and to find ways on a system-wide basis to expand testing and the availability of testing for those veterans.

Mr. **Steinberg**. I think your answer was: I think that is the policy?

Dr. **Gronvall**. I am not aware of whether we have issued a formal directive or policy statement to say every medical center should begin taking steps to aggressively offer testing to all veterans who are in drug treatment programs.

Mr. **Steinberg**. Is that a good policy?

Dr. **Gronvall**. Dr. Cohn should really comment on that. It is certainly a good policy, and it is, as I say, under development to expand.

Dr. **Cohn**. As I said in the earlier testimony, when we first appeared, the two cardinal areas in which we have given guidance are the use of the test as an aid in the diagnosis of AIDS or ARC—so a clinical indication clearly—and a second indication, of course, is the use of the AIDS antibody test in Project Lookback, the transfusion-related AIDS. Those are the two areas where we have issued specific guidance. We have had discussions on individual bases with various chiefs of staff, but there is no specific language addressing that.

Mr. STEINBERG. And I think I understood the Chief Medical Director to say that he believes that would be a good policy?

Dr. COHN. That is what we are in the process of developing. That is the position paper that was alluded to considerably earlier this morning.

Mr. STEINBERG. And that would apply not only to drug patients, but there are certain other connected conditions and certain other indications that individuals may be in high-risk categories. Is that correct?

Dr. COHN. Yes.

Mr. STEINBERG. And how long will it take, would you think, to get specific guidance to your medical centers, encouraging them to aggressively offer the test to persons in those categories?

Dr. GRONVALL. It is a little hard for me to put a specific date on it because the recommendations we have been developing are planned for deliberation at the Domestic Policy Council and I believe a presidential decision or an Administration decision about what the character of the expanded testing will be in the Veterans' Administration. I think that will require that that kind of decision be made. We are working on the details, of course, of such an expanded program, what the costs and other implications would be, the need for counseling, and all of the other attendant things that would have to be done to make a major expansion of testing of the sort we are describing.

Mr. STEINBERG. You think what we are talking about here is a major expansion? I am sorry. When I say here, I mean in the last 5 minutes.

Dr. GRONVALL. I don't know about the definition of the word "major," but for us to adopt as a VA system a system-wide set of programmatic requirements that, through all of our drug abuse programs or substance abuse programs, we explicitly expand the counseling of every veteran, to encourage every veteran in those programs to be tested and to followup with counseling on the results of the tests would be a significant expansion of testing in that aspect of a VA program.

Mr. STEINBERG. Testing and counseling?

Dr. GRONVALL. Yes; testing and counseling. When I say "testing," counseling is presumed to be a part of that. And like any other program that we want to adopt system-wide, it requires some thought to ensure that we have a realistic timetable for doing it, that we make the resources available, the guidance available, that we have the staff who can do it, et cetera, et cetera.

Dr. SIMBERKOFF. I would just like to make one additional comment. That is that we have had an ongoing study in our drug abuse program—our Methadone Maintenance Program—which actually began almost 4 years ago, a progression study of the patients for immunological dysfunction, which actually began before HIV was recognized. Retrospectively, it was shown that HIV was the cause of the immunological dysfunction that was being observed and followed in these patients.

It now includes most of the patients that are being followed in the Drug Detoxification and Methadone Maintenance Program. One of the biggest problems that we have in our facility, as well as one of the biggest problems that is present in all of New York City, is the fact that our programs are filled. There is no room for additional individuals to be included in the Methadone Maintenance Program. We have difficulty, when new patients come into the hospital and wish to be entered into drug detox or Methadone Maintenance Program, of finding an available place for them.

So, it is more than simply expansion of the availability of testing programs and counseling programs. One has to also have available for patients places where they can be given the type of treatment that is necessary to allow them to stop the high-risk activity which leads them to the infection in the first place and may result in further spread of the infection, even after it is known that it is present.

Mr. STEINBERG. I think we understand the problems of resources and, indeed, Senator Cranston had a number of comments about what demand on resources might be made by a substantial expansion of testing. I must say I find it strange, I suppose, that we would be talking about what I think nobody as a matter of policy would quarrel with, that is, that we ought to be trying to get more people who are at high risk for having the virus tested. I mean, certainly all the testimony this morning was to that effect from the Administration and from all our witnesses and from the three of you. And Dr. Gronvall has very carefully indicated—and I am sure very properly—serious reservations about moving ahead too quickly with any such policy until we know the implications, until we are sure that it would be done right, until we are sure we would have the resources in place to do it.

And yet, there are apparently some people in the Administration somewhere—if one believes the New York Times—who believe that we can put in place in our lifetime a program of testing all 1.4 million VA hospital admissions a year. And I find your testimony very careful and appropriately cautious about doing this in a clear high-risk category where everybody agrees that it is good public policy. Whereas in the area of 1.4 million, I think it is fair to say not everyone would agree that it is good public policy. Indeed, the burden of our testimony this morning is that it is not; and yet, that is being seriously looked at, even though the implications for resources and doing it properly, are so substantial for what appeared to me to be a very modest expansion of what is going on.

Now, I just have to surmise from that, regardless of what policy dictates may be considered or may be made actually, it is going to be a long time before the VA would ever have in place a program where it could test all 1.4 million hospital admissions. Tony, I don't know if you have any thoughts to share on that. It just struck me as interesting, particularly in light of Senator Murkowski's concerns, which Senator Cranston shared, about trying to get certainly high-risk people tested. How would we go about doing that? It is obviously not as easy as talking about it.

Let me ask a couple of questions about the ELISA test and your costs, if I may, for that test and for the Western blot confirmatory test. How much contracting are each of you doing? How much of it is being done by sending the samples to Lexington? Do you want to start, Dr. Crow?

Dr. CROW. Sure. We are doing all of our ELISA testing in our facility—all of it.

Mr. STEINBERG. You are doing it yourself?

Dr. CROW. Yes, we are; that cost is running us, I think, about $5.50 per test—per patient if you will. At the present time, Mr. Steinberg, we are not sending out routinely confirmatory tests because right now we are in the process of primarily testing patients who are at high risk and therefore have a very high prevalence of disease. The use of the confirmatory tests, such as the Western blot or some of the others, we think has very little value.

We have sent the confirmatory tests——

Mr. STEINBERG. Is that because these people are symptomatic? Is that what you are saying?

Dr. CROW. That is because these people are symptomatic and/or in a high-risk group, where the prevalence is high and therefore the incidence of false positives is very, very low, as was made reference to earlier.

The confirmatory test, that is, the Western blot, we have used in areas where a patient may have a symptom complex that is consistent with HIV infection but not be in an identified risk group; in that setting we will routinely send out the confirmatory test. I am sorry that I don't know the cost of that particular assay. We do send it out. I don't know whether it goes to Lexington or some local contractor. I don't know.

Mr. STEINBERG. Dr. Gordon, I will get to you in just a moment. Mr. Crow, you are saying that you would make a finding or diagnosis that an individual does have the HIV virus and enter it into the medical record without a confirmatory test, as long as there is a positive test result the first time on an ELISA test for a high-risk person. Is that correct?

Dr. CROW. We do two ELISA, if you will. The test is done twice before it is called positive; if it is positive on both determinations, then we call that a positive test. Given the patient's situation, if that is a likely diagnosis, then, yes, we will enter that into the medical record.

Mr. STEINBERG. Would each of you comment on that issue specifically and answer the question generally about your experiences with the ELISA test and the Western blot in terms of cost and contracting? Dr. Gordon?

Dr. GRODON. Up until this point in time, we have sent all of our tests—the ELISA as well as the Western blot—to be done at Lexington. I have the impression that they are to their full capacity; and if we are to expand voluntary testing, we would have to go to the open market. For the ELISA, this would be $30 that we could get it for with the UCLA Medical Center through our sharing agreement. The Western blot would cost us $104 at Smith-Klein.

But I think for a limited number, we could handle this within the funding that we have recently been provided. In addition, we do spend a fair amount on T-4 cell tests, which we get in the local community for $45 a test.

Mr. **Steinberg**. This is to determine the extent to which the immune system is impaired?

Dr. **Gordon**. That the immune system is impaired.

Mr. **Steinberg**. Do you want to comment on the point that Dr. Crow made about when an individual in a high-risk category is diagnosed as having the virus? I was surprised to hear that. I had thought that the Western blot test was routinely done. So, that is why I am asking you each if you would comment on it?

Dr. **Gordon**. As far as I know, the Western blot is only done on those that have a positive result.

Mr. **Steinberg**. That is what I am saying. Dr. Crow's testimony was that, in the high-risk individuals and in individuals who are symptomatic, if they have two positive ELISA results, they do not test further.

Dr. **Gordon**. Oh, I see. I can't answer that.

Dr. **Simberkoff**. Our practice is actually to do ELISA's, Western blots, and T-4 lymphocytes, all in the house. It has been done in Dr. Susan Zolla-Pazner's laboratory. She actually was one of the pioneers in describing the immunological abnormalities of AIDS. She has been following the immunological abnormalities as well as determining the prevalence of AIDS antibodies in the population.

The costs of the tests, I think, are comparable to those that have been quoted. I understand that the ELISA costs around $5, the Western blot somewhere around $20. The costs of all of these tests are sort of artificial in the sense that a group of technicians that does all of them, their salaries are not included.

Mr. **Steinberg**. Right.

Dr. **Simberkoff**. It is mainly for reagents. It is actually our practice to do all tests in anybody who is positive, in other words, if an ELISA is confirmed by a Western blot. We would have great reservations about not confirming a test or reporting a test as positive if it were not confirmed and certainly also not determining the patient's immunological status prior to talking to them. We think it is very important to give both him (the patient) as well as ourselves an idea about the extent of immunological dysfunction that is present so that we can more intelligently discuss with him what he might expect.

Mr. **Steinberg**. So, that is why you do the third test in all cases?

Dr. **Simberkoff**. Right.

Mr. **Steinberg**. Does your laboratory also do testing for the other New York facilities—the VA New York facilities?

Dr. **Simberkoff**. They have on occasion sent serum to us.

Mr. **Steinberg**. But it is not routine?

Dr. **Simberkoff**. It is not on a routine basis. I think that we have encouraged them to do so, but for whatever reasons they have chosen in most cases to send them to other laboratories.

Mr. **Steinberg**. It sounds like—Dr. Gronvall, if I might interject—that if we move into larger testing programs, which it seems to me you are going to inevitably do, certainly for high-risk individuals, that perhaps the Manhattan, if appropriately augmented, might be able to serve as a resource for the east coast at least, rather than our having to go out into the marketplace and pay four, five, or six times the cost of an in-house test. I am sure you will look at that.

Dr. GRONVALL. Oh, absolutely. And you made the comment earlier that, even when we were talking about the perhaps modest expansion of testing that would be carried out through veterans in our drug abuse program, as we look ahead I think it is quite clear that we are going to be significantly expanding testing, under whatever banner that program is developed. And one of the reasons why I earlier was exercising restraint in talking about how soon we could do that and to what extent is that we are looking at all those options.

We do have half a dozen of our medical centers now able to do the full array of sophisticated testing; but we want to be sure that, before we make any specific projection of a major expansion of testing, we have the capability, have the plans in place, know which laboratories will be expanded, what the costs and other implications of that are, and so on.

Mr. STEINBERG. As I said, I thought that was most prudent and appropriately cautious.

Dr. GRONVALL. I appreciate it.

Mr. STEINBERG. Do you have any comment, Dr. Gronvall, on the issue of confirmatory tests? Does the department have a policy? My concern is that, once it is entered into the medical file—as it would be for example in Houston—that the individual has been confirmed as having the antibody and presumably having the virus, that is a pretty serious matter for that individual medically, socially, and in every way.

We have received considerable testimony that certainly the VA can't guarantee the confidentiality of the medical record and that that information might become available to an insurance company or who knows whom else. I am just wondering if you were surprised to hear that as well?

Dr. GRONVALL. Let me ask Dr. Cohn to comment and to speak to the departmental policy because we have addressed that issue.

Dr. COHN. Every consideration, every discussion, every policy pronouncement, every meeting I have ever been to, I have always heard that one must perform the Western blot as a confirmatory if either of the first two ELISA's are positive.

Mr. STEINBERG. Is that departmental policy?

Dr. COHN. Yes, sir, in the areas which I addressed in my earlier response to you.

Mr. STEINBERG. If someone is tested, and the test is positive——

Dr. COHN. This is the ELISA you are talking about?

Mr. STEINBERG. Yes. Is it Department policy that there shall be at a minimum a confirmatory Western blot test, perhaps a second ELISA test? But at a minimum, there should be a confirmatory Western blot?

Dr. COHN. Yes, sir.

Mr. STEINBERG. And is that written policy?

Dr. COHN. As it relates to the two programs I have mentioned. Yes, that is the policy.

Mr. STEINBERG. We are saying that the test has been performed in a VA facility?

Dr. **Cohn**. Yes, but your line of questioning has moved over into another, broader area. I can only address the policy issue related to the testing that we have spoken about in policy.

Mr. **Steinberg**. No, I am only talking about the actual testing that is going on at the moment. As to testing that is going on at the moment, which could be pursuant to either of the programs that you indicate, or because somebody voluntarily requests to have a test made——

Dr. **Cohn**. The Western blot should be done as a confirmatory.

Mr. **Steinberg**. And since that apparently is not being followed throughout the system, I would suggest that perhaps there is a need to reinforce that policy through a written issuance, but perhaps as well through one of your phone conferences.

Dr. **Gronvall**. You yourself made the comment earlier that one of the ways that information surfaces and circulates is through congressional hearings. We appreciate the surfacing of this question today, and we will certainly followup on it.

Mr. **Principi**. I would like to ask a question. I sense that it sometimes becomes a blurring of civil rights and medical issues. Certainly, first and foremost in my mind, is the fact that AIDS is a medical issue and not a civil rights issue, notwithstanding the fact of the need for privacy and confidentiality. The lack of any absolute certainty with respect to confidentiality and assuming that you do the requisite ELISA test and Western blot, is there medical justification for placing the findings in the medical records? Is that most important from a medical-clinical perspective?

Dr. **Simberkoff**. In my opinion, it is because it alters the differential diagnosis, that any physician seeing this patient might wish to entertain for any set of symptoms or signs that that patient exhibited. Knowing that this individual has been infected by HIV will certainly alter his susceptibility to a variety of infectious agents and make him a more likely candidate for a number of malignant diseases.

We have already said that sometimes these patients go to different clinics and are seen by different physicians on different occasions. These physicians—whether it be an oncologist or an infectious disease specialist, a gastroenterologist or a pulmonologist—will be thinking about different diagnoses if they know that that individual has HIV infection and a set of symptoms than if that individual is not known to have HIV or just a person appearing off the street with that same set of symptoms.

Mr. **Steinberg**. Dr. Gordon.

Dr. **Gordon**. From my early comments, I have great concerns about confidentiality. This can mean loss of life insurance, health insurance and, goodness knows, what else. This is why I have taken a more strict approach, but we do make certain that the primary physician gets the report verbally so that those who are caring for the patient who have a need to know, do get the report verbally. Now, this does have drawbacks to it, and it is going to be an increasing problem if we expand our testing voluntarily to other groups.

It is a real concern to us, and perhaps you can help in the legislative field.

Mr. **Steinberg**. It is pretty clearly a no-win situation.

Mr. **Principi**. It sounds like it.

Dr. **Crow**. I think that result does have to be in the medical record. From a medical care standpoint, I believe the access has to be there. I do think the possibility of discrimination in the social sphere is a real one, though I will also admit it hasn't developed to the extent that I was afraid it might, at this time 2 years ago.

But I do think that the availability of the result in the medical record is important. As Dr. Gordon described, in Houston we have taken efforts not to put that result in the computerized laboratory profile of these patients, but instead, by hospital policy, ask that it be included in a progress note.

Mr. **Steinberg**. Dr. Cohn?

Dr. **Cohn**. May I say something.

Mr. **Steinberg**. Please.

Dr. **Cohn**. I would like to borrow on the words of Jim Curran. He didn't say it today, but I have heard him speak a number of times; and I have a lot of respect for him.

The reason why it would appear that perhaps we are struggling and we have some differences of viewpoint is that we are living—literally living—through this epidemic, and it is obviously very complex. Every issue we discuss within it—whether it is confidentiality, drug treatment, vaccine development, or what have you—is an extremely complex issue.

So, it is little wonder that we do have some differences of view and differences in terms of where records are kept or where they aren't. I think we clearly need stronger confidentiality laws, and I have expressed that in House hearings; and I think the Congress can help us there. So, I don't find it at all surprising, indeed, that we are having some trouble coping because we are living through a very serious epidemic.

Mr. **Principi**. Thank you, Jonathan.

Mr. **Steinberg**. As I said, this is pretty much a no-win situation. I would have to comment to Dr. Gordon that we don't have complete continuity of care in the VA, and, obviously, the fact that a physician has been advised of the result of the test—and we are talking about a positive result in terms of the points that Dr. Simberkoff and Dr. Crow have made—does not mean that a subsequent physician treating that patient will ever know it. It grieves me to make that comment because I admire your tremendous sensitivity to the confidentiality neads of your patients in this regard.

And I share completely your view that, once it is in the medical record, it is very difficult to protect that information. I think it is impossible to protect it, and I don't know where this can lead, but it is very troublesome to me.

Dr. **Gordon**. As I indicated, this does have some drawbacks and this has been of concern to me and particularly as we get higher numbers of patients. This is another reason why I have appointed an AIDS coordinator, so that at least we can have continuity.

Mr. **Steinberg**. But that is not going to deal with this particular issue because these people are asymptomatic by definition.

Dr. **Gordon**. Oh, yes.

Mr. **Steinberg**. Dr. Cohn mentioned the confidentiality concerns and the need for stronger laws, and we have submitted a written question to you on that; but I am somewhat puzzled as to what the law can do in this situation that can really control human nature and human behavior in a hospital setting.

When it becomes known, and it is there in the medical record, that this individual is antibody positive, virtually everybody on that ward, if not on that floor, involved with patient care is going to know that. I think that is going to follow, and I presume some would say they should know that. Dr. Simberkoff, you are shaking your head.

Dr. **Simberkoff**. In the first place, I think when you reach a situation where a substantial number of patients are known to be either HIV positive or to have AIDS, the significance of any one individual having that diagnosis tends to diminish.

Mr. **Steinberg**. Meaning it is not necessary to be known for purposes of protecting hospital workers?

Dr. **Simberkoff**. Exactly. One of the other hats that I wear in the hospital is Chairman of the Infection Control Committee. The AIDS problem has taught us the importance of stressing appropriate infection control practices on all individuals at all times.

Mr. **Steinberg**. Right.

Dr. **Simberkoff**. In a hospital in which the prevalence of HIV may be very high, and certainly that is true of all three of our institutions, we have to assume that every patient that we see at almost every encounter might be infected. So, the appropriate practices are necessary, as was stressed by one of your previous witnesses from the American Nurses' Association.

Mr. **Steinberg**. Right.

Dr. **Simberkoff**. And I think this has certainly become the case in our hospital where we are now stressing mandatory wearing of gloves for all blood drawings, transportation of blood specimens in an appropriate fashion to the laboratory and the handling of all bloods in the laboratory with gloves and appropriate precautions. This is done so that the accident which may occur with the blood tube which has not been labeled will be avoided and so that we don't have to worry about labeling only those individuals that we recognize.

I think that the experience that Dr. Curran referred to with the three health-care workers where AIDS was not even suspected, needs to be a lesson to us. Even after the problem of HIV has been solved, there will be other viruses. We currently can think of non-A, non-B, as being a potential infectious agent transmitted by blood; and there certainly are other retroviruses, perhaps HIV-2 or other viruses, which will be coming along in the future.

We have to stress for the future infection control in handling all blood specimens and alter our practices now using AIDS as the example.

Mr. **Steinberg**. That is certainly excellent advice. Dr. Gronvall.

Dr. **Gronvall**. I would like to make a comment on this issue of the medical record. I believe that, whatever else AIDS is, it is at heart of course an infection with a virus that leads to a tragic disease; and it is at heart a medical issue. For the long pull then, I at least always want to come down on the side of creating a record for each individual veteran patient who comes to us that is full, accurate, and contains the best possible information that is relevant to the medical status of that veteran.

I am extraordinarily concerned about the confidentiality aspect, but I believe we have ways of working on that. I would never guarantee the confidentiality of a medical record because I think that is not humanly possible; but I believe we can work on that. There have been many references to the fact that we are at the early stage of this pandemic, and most of the questions cannot be answered with clarity. That surely is true, but it is to me absolutely predictable that at some time in the future—hopefully it will be in the near future—there are going to be new advances.

There will be either drugs that can arrest the progression of the disease, hopefully even drugs that could eradicate the virus, and then ultimately a vaccine that could prevent it.

At the point, let us say, where a drug is developed that can eradicate the virus, I want us in the VA to be in the position of having the medical information available as to veterans that have been infected but are, at that time, not yet symptomatic so that they can be contacted, and we can make available that treatment. So, as I look down the road, that and a lot of other speculative questions that you could pose, it seems to me, all will be benefitted by having accurate, comprehensive, and clear medical information that is available about each veteran patient that we are caring for.

So, I come down, as I said earlier, on the side of treating this as a part of the medical record.

One other comment. I guess I don't like to think of myself as a senior physician in terms of age, but I am old enough to remember that, when I first was in medical school, at that point I even heard the remnants of somewhat similar discussions about cancer—not entirely a comparable situation. But there were people that I remember having heard say that the information about a patient's cancer should not be specifically documented and that the individual and the family should never know about this because no one could live with that terrible knowledge, and it would destroy the individual. Well, over time, I always want to come down on the side of the information and the informed and explicit honesty in dealing with our patients, always working on their well-being and the well-being of the people around them.

And I think again, in the long pull, that can only be done when we have honest, accurate, full, and concrete information that puts our health-care delivery team in the best possible position of having the tools to deal with each individual veteran in a compassionate and humane way, bringing to bear the best that modern medical science has to offer.

And surely, the position that we are in right now is not where we are going to be even 6 months from now or a year or 2 years or 5 years from now. So, I am willing to build the record on that basis.

Mr. **Steinberg**. Let me note that we are very anxious to know whatever specifically you believe needs to be done to improve the confidentiality laws. We will be sending this afternoon a question with respect to that. We would appreciate a rapid response.

My comment was only that laws, Dr. Gronvall, can only do so much. And as you said, you cannot guarantee the confidentiality of the record. I feel very badly that we have brought our constituent all the way back here from Los Angeles and here he has found that he is in a sort of minority position on this. And the same thing has happened in one respect with respect to Dr. Crow. I am sure if we go on long enough, we will find one for Dr. Simberkoff also. [Laughter.]

And I trust that it need not be said—but rather is understood—that everyone here is obviously doing what they think is in the best interest of their patients—in the total interest of their patients—and if those things are not 100 percent in accordance with policy, then compliance can be brought about in appropriate ways, but that everybody has been proceeding in what they think is in the best interests of good health care. I am sure that that is understood, and that is a part of the context in which we are operating, although this is on the public record and this isn't a confidential or private forum. I sort of feel as though an apology is in order to each of you. We don't do the kind of extensive pre-hearing preparation that is done for the Iran Committee—I guess except in the case of Colonel North—and so, we don't know what answers we are going to get to all the questions.

If we get anybody in trouble, we apologize; and I am sure there won't be any trouble. Is that fair to say?

Dr. **Gronvall**. Oh, Mr. Steinberg, let me comment on that; I think quite to the contrary. We are living through an evolving pandemic, as we have all described. I have no belief that a major contribution to our ability to deal with this would be brought about by my issuing every day, or every other day, a uniform set of rigid rules and ensuring that everyone complied with them.

Mr. **Steinberg**. You will leave that to the Congress, is that right? [Laughter.]

Dr. **Gronvall**. I have a great deal of help on that issue from a lot of people here in Washington. In fact, I referred earlier to the genius of America, being that I think if we in the Central Office can help focus what the problem is, what the tools are that can be made available, it is in fact to our benefit to encourage and watch the creativity and innovative approaches in our individual medical centers; and in a collective way, we learn from that experience, and we have medical centers that are handling this issue in very different ways. In each case, there is a responsible physician and medical staff responsible; and differences in approach, I think, are not only acceptable but are in fact desirable as this disease unfolds before our very eyes.

So, I am not at all concerned to hear differences of approach being described.

Mr. **Steinberg**. Good. Tony, go ahead. I have only one last piece of information I want to address.

Mr. **Principi**. I have to depart, but I just wanted to say that this is probably the most informative hearing that I have had the privilege of participating—probably the longest in recent memory. [Laughter.]

I just want to thank the witnesses for their insightful comments and their contribution to this issue. Speaking on behalf of Senator Murkowski and other members on this side of the aisle, thank you very, very much.

Mr. **Steinberg**. Thank you. We certainly share in that view and thanks. I should close this hearing, but there is one other piece of information I would like to get, and then I will certainly echo Tony's sentiments.

If an individual tests positive on the first test, and then a followup test is done—either another ELISA or the Western blot—and it is determined that that was a false positive, is there any notation in the medical record of there having been a false positive? Or is there just a final notation that it was negative?

Dr. **Simberkoff**. That would be recorded as a negative, if it was truly a negative. Now, there are circumstances that I think you have to be aware of where one can get an equivocal Western blot, which would require——

Mr. **Steinberg**. Now, I am just saying that where it was determined that it was a false positive, it would never be shown as a positive of any sort?

Dr. **Simberkoff**. Right.

Mr. **Steinberg**. Dr. Gordon, in your system, would that be the case as well?

Dr. **Gordon**. If we got a false positive back, you know it would take time for us to become aware of this. Right?

Mr. **Steinberg**. It would depend on the circumstances.

Dr. **Gordon**. But certainly, this should be corrected, and the patient has to be called in and this explained, and the record changed accordingly.

Dr. **Simberkoff**. In our case, the patient wouldn't be informed until the confirmatory test was done; and no information would then be put on the chart concerning the initial false positive finding.

Mr. **Steinberg**. Dr. Crow, do you have any comment?

Dr. **Crow**. Sure. The way we are going to handle that is to note it in the medical record. Now, the issue of going back and changing the prior medical record—since we report our results in a progress note—would certainly be a problem. I don't think I have a response for that, Mr. Steinberg.

Mr. **Steinberg**. So, we do have, in essence, two or three different policies. And I won't pursure this further because I don't know what the answer is. But it is an interesting issue, and perhaps it ought to be looked at as to what ought to be done, whether or not there should be a progress file type of note or whether or not the file should——

Dr. **Simberkoff**. We could go on forever, but I think it has to be pointed out that there are many reasons for false positives, including the fact that there may be other retroviruses present, which can give false positive reactions, and which become very significant in terms of followup of patients.

Mr. **Steinberg**. Right.

Dr. **Simberkoff**. So, this is one of the other things that has to be looked for.

Mr. **Steinberg**. I am far in over my head.

Let me conclude by echoing what Tony said, and again regretting that Senator Cranston could not remain here. As you know, he was here in excess of 3 hours. We thought it was very important to cover as many topics as we could with the Administration witnesses and the other witnesses.

Your contributions have been of enormous assistance to all of us. We thank you for your time and for traveling here. Let me note in closing how much the committee appreciates the policy of Dr. Gronvall and his staff. All of the witnesses, I should note for the record—not just Dr. Gronvall and Dr. Cohn, but Dr. Mather, Mr. Lindsey, Dr. Greene, and Mr. Ibson—have remained here through this entire hearing. We greatly appreciate that degree of attention and the obvious concern that it manifests.

We think that is an excellent policy. And I know the committee would want me to thank you very much for your courtesy to the witnesses and to the committee and for your show of commitment. We stand adjourned.

[Whereupon, at 2:10 p.m., the hearing was concluded.]

APPENDIX

STATEMENT OF
JOHN A. GRONVALL, M.D.
CHIEF MEDICAL DIRECTOR
DEPARTMENT OF MEDICINE AND SURGERY
VETERANS ADMINISTRATION
BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE
JUNE 24, 1987

Mr. Chairman and Members of the Committee:

I am pleased to be here today to provide the Committee with an update regarding the impact of AIDS (Acquired Immune Deficiency Syndrome) on the Veterans Administration.

The Epidemic in the U.S. and VA Experience

AIDS is a devastating disease. It is but one manifestation of HIV (Human immunodeficiency virus) infection. In the United States over 36,000 cases of AIDS have been reported to the Centers for Disease Control (CDC). Over 1.5 million people in the U. S. are thought to be infected and many feel this is a conservative figure with estimates ranging as high as 4 million but no one knows for sure. HHS will conduct an epidemiological study to determine the incidence of AIDS in America. In terms of those who will go on to develop symptomatic disease, the estimates range from 25-70%. The cumulative death rate is over 55%; the case fatality rate is approximately 85% for those who have the disease for three or more years. No cures have been reported.

The VA's case load has ranged from 5.3 - 5.8% of the total number of cases reported to CDC. From September 1983 to May 1987, 2,014 cases of "full-blown" or CDC-defined AIDS have been reported to VACO. Ten (10) VAMCs have reported 1,194 of these cases or approximately 60% of the VA total. The Centers with the highest number of cases reported during this period are:

New York (Manhattan) - 324
West Los Angeles - 131
San Francisco - 118
Bronx - 118
Miami - 102
Brooklyn - 99
East Orange - 95
Houston - 75
San Juan - 73
San Diego - 59

One hundred eleven (111) VAMCs have reported at least one case. The impact on the VA is therefore differential in character: moderately-heavy on several of our Centers, minimal on the majority. The VA Medical Centers in New York State have treated nearly 30% of the total, those in California 21% of the total. Based on the data presented at a conference sponsored by the Department of Health and Human Services in June, 1986, in Berkeley Springs, West Virginia, the situation is predicted to worsen dramatically by the end of 1991: 270,000 total cases cumulatively with nearly 180,000 deaths, again cumulatively, since the beginning of the epidemic in 1981. These figures are now being revised upward due to a modification of case definition by CDC. The VA's cumulative caseload could equal 14,000 cases by 1991 based on these data. However, it is anticipated that the Department of Defense policy on screening all active duty personnel and recruits could modify the VA's future case load. Because the veteran population is composed of relatively few females, increasing numbers of women and children expected to be affected in the future will have less impact on the VA than society at large.

The treatment of AIDS patients is both labor-intensive and cost-intensive. A host of medical specialties and subspecialties are involved, as well as a significant number of staff members from a variety of allied health arenas, including Social Work Service, Pharmacy, Chaplaincy, etc.

Laboratory Support

Laboratory Testing for the antibody to the AIDS virus serves a variety of clinical purposes including: (1) part of the diagnostic work-up of a patient, (2) part of the "look-back" program to determine if patients transfused with blood or blood products prior to the availability of the ELISA test (3/85) are antibody positive, (3) voluntary screening of individuals or groups at high risk, (4) corroborative or confirmatory testing (the use of the Western Blot to confirm a positive ELISA), (5) "tertiary" testing - the performance of sophisticated studies to determine the status of a given patient's immune system (e.g., T4/T8 ratios).

The VA has provided guidance to its field facilities that testing for the antibody to the AIDS virus should be performed when clinically indicated, i.e., in aiding in the establishment of a diagnosis, and in collaboration with the various blood banking associations in the U.S. (project "look-back").

In response to the challenge of AIDS, the VA has expanded the Reference Center for Serology at VAMC Lexington to serve the agency as a laboratory to test for HIV antibody. This facility provides both screening and corroborative testing. Growth of this service has been exponential as AIDS cases have increased, resulting in maximum productivity by the laboratory.

The increased pressure for AIDS testing at VAMC Lexington with its rapidly mounting costs has resulted in the development of a new and innovative method for financing this program, referred to as the "charge back system." This will allow VAMC Lexington to charge other VA medical centers for AIDS testing services. The cost to the VA for screening tests is approximately $5.00 per test and the cost of the corroborative test is $17.00 per test. The cost for this testing service on a fee basis arrangement in the private sector would range from $12.00 to $30.00 and from $25.00 to $45.00 respectively for screening and corroborative procedures.

In 1985 the VA anticipated the approaching demand for tertiary testing for AIDS which requires a flow cytometer and monoclonal antibodies. To meet this need, the VAMCs in New York, Albuquerque, San Francisco, Denver and New Orleans were provided with this technical capability.

The cost to the VA to perform tertiary testing by flow cytometry will vary from $90.00 to $120.00 per specimen depending on the number of monoclonal antibodies used. This same service on a fee basis arrangement ranges from $400.00 to $600.00 per specimen in the New York area.

Costs of Caring for AIDS Patients

There have been numerous attempts both in the VA and out to arrive at cost projections per case. In order to be responsive to facility needs, we have attempted to find a more rational way of funding facilities for AIDS cases. As you know, a facility's resources are based on workload performed two fiscal years prior. Because AIDS is a relatively new disease that is increasing at a rapid rate and is unevenly distributed around the country, it is a special challenge for the few hospitals that care for the majority of the Agency's AIDS workload.

Several months ago a questionnaire was devised that was sent to 11 facilities that had a high number of reported AIDS cases. The questionnaire asked them for certain information concerning their last 10 AIDS patients in FY 1986. Using this data, we estimate that our Resource Allocation Methodology has provided funding of approximately $6,000 per AIDS case to VA Medical Centers.

In FY 1985, we estimated that it cost $38,000 per year to treat an AIDS patient. A more recent study determined that $24,000 a year would be more appropriate.

Based on reduced lengths of stay, less use of intensive care unit days and better facilities to manage these patients, it is believed that the cost of an AIDS patient has decreased about 20% since FY 85. As a result, we are using $20,000 as an estimate of cost per patient per year for FY 1987. Based on this, supplemental funding has been provided for those facilities that have seen more than 15 cases in FY 1987.

Although costs do appear to be coming down, the treatment outlook is unchanged (except for the emergence of zidovudine, formerly called AZT - for selected cases). Increased use of this drug will offset reduced costs. The drug itself costs from $7-10,000 per year per patient. Also, since the drug is toxic and requires close monitoring, including various laboratory studies, additional costs are incurred.

Intergovernmental Coordination

We are working closely with other Federal agencies to coordinate activities related to this epidemic. An example of one such partnership is the DoD/VA Working Group co-chaired by Dr. H. D. Cohn of the VA's Department of Medicine and Surgery and Captain V. Schinski from the Assistant Secretary of Health's Office in DoD.

The purpose of the DoD/VA Working Group is twofold:

(1) to exchange recent and evolving research and clinical developments

(2) to work toward effecting the smooth transfer of patients with AIDS or the lesser syndromes (e.g., ARC) from the military to the VA health care system. (It is projected by DoD officials that approximately 550 persons will be medically discharged from the three services over the next two years, potentially seeking continuation of their care in the VA).

The VA has also been an active participant in other groups, including the White House Working Group (WHWG) on AIDS, a group now chaired by Mr. Gary Bauer, Policy Advisor to the President. Discussion continues in response to a decision by the President to review all Federal programs where expanded testing would be appropriate. Dr. H. D. Cohn also serves on the Federal Coordinating Committee on AIDS Information Education and Risk Reduction and represents the VA on the Intragovernmental Task Force on AIDS Health Care Delivery.

Education Activities

In addition to the provision of high quality clinical care for patients with AIDS or ARC, the VA, of course, has a heavy commitment in terms of educating its health care workers. In this regard a variety of educational programs have been conducted throughout the system:

- 30,500 VA staff trained in FY 1985 at 129 VAMCs involving individuals from all Services.
- 13 RMEC (Regional Medical Education Center) sponsored AIDS programs in FY 1986 - 1,530 VA participants
- 12 CE activities sponsored by CHEPS (Cooperative Health Manpower education Programs) in FY 1986 - 545 VA participants
- 3 RMEC sponsored AIDS programs in 1987 - 440 VA participants - others in planning stages (Birmingham - Cleveland - Seattle*).
  - * held May 14-15, 1987
- 15 Dental Education Center sponsored programs - 980 VA participants

The VA is participating in the Red Cross "Look-Back" program which is designed to offer the AIDS antibody test and appropriate counseling to patients who received blood transfusions between the years 1978 and 1985. Also, the VA has participated in the distribution of the U.S. Surgeon General's Report on AIDS.

Mr. Chairman, as you suggested during your May 21, 1987, hearing, we intend to expand patient health education efforts targeted specifically to groups at higher risk of developing AIDS.

Research

The VA is engaged in the entire spectrum of research on AIDS from basic science studies of the mechanism of AIDS virus infection, through clinical trials of drugs in the treatment of veteran patients with AIDS.

In the area of basic research, a number of VA laboratories are studying the mechanism by which AIDS virus infects cells. Dr. John Ziegler of the San Francisco VAMC is studying the molecular events, triggered by AIDS virus infection, that result in the death of essential cells of the immune system.

Dr. Paul Hoffman of the Baltimore VAMC is using a mouse model of AIDS infection to understand how the virus attacks and kills nerve cells.
Dr. Bernard Poiesz of the Syracuse VAMC has been investigating the mechanism by which viruses, similar to AIDS virus, cause certain cancers of the lymphatic system in animals. This area of research is important to our understanding of why some AIDS patients develop these kinds of cancers. In other animal studies, Dr. Stephen Wright of the Salt Lake City VAMC is working on a vaccine for an AIDS related animal virus.

In the three years since it became established, the Virology Reference Center at VAMC West Haven has gained a nationwide reputation for service and excellence. While the Center has elected to continue offering standard viral serology services as its major mission, it has also established a laboratory for the culture of the AIDS virus. An anticipated benefit of this service will be to enable the center to test the effect of new drugs on the AIDS virus. West Haven is the only VAMC with the capability to grow this virus.

In the area of clinical research, Dr. Susan Zolla-Pazner of the Manhattan VAMC is investigating the impact of AIDS virus infection on the functioning of the immune system, and Dr. Michael Simberkoff, also of Manhattan, is attempting to improve therapy for the serious infections that attack AIDS victims because their immune systems malfunction. Dr. Wallace Tourtellotte of the West Los Angeles VAMC and Dr. Peter Dowling of the East Orange VAMC are studying infection of the nervous system in patients with AIDS. A number of other VA investigators (Drs. Dobbins, Ann Arbor, and Klotman, Durham) are studying "opportunistic infections" in AIDS patients.

Several VA investigators are actively engaged in the development and testing of new drugs for the treatment of AIDS infection. Dr. Raymond Schinazzi of the Atlanta VAMC is designing new drugs targeted against the unique biochemical pathways of the AIDS virus. Drs. John Bilello and Paul Hoffman of the Baltimore VAMC are supported by the NIH to test new, potentially useful drugs against AIDS. And the VA is carrying out a large scale, controlled clinical trial of the efficacy of zidovudine, formerly called (AZT) treatment in patients with AIDS-related complex (ARC). This trial is supported by special AIDS research funds from the Department of Defense.

Concluding Remarks

Dr. Jonathan Mann, AIDS Program official with WHO (World Health Organization), has described three phases that nations undergo in coping with the AIDS "issue" or the first AIDS case they encounter:

Phase 1 - minimization
Phase 2 - reluctant acknowledgement
Phase 3 - constructive engagement

These "phases" are probably quite representative of what municipalities, other forms of governments and health care systems experience. We believe that the VA, although the system is affected differentially as pointed out above, has embarked on its own constructive engagement phase.

In terms of planning for the future, the following concerns or actions occupy our attentions.

(1) Continue to cooperate with other Federal agencies (DoD, DHHS, etc.).
(2) VA internal cost accounting and reimbursement methodology are under continuing review.
(3) The feasibility or desirability of identifying "AIDS Centers" in medical centers located in the epicenters of the epidemic.
(4) Continuation of the zidovudine (AZT) clinical research trial in patients with ARC.
(5) Education remains a key ingredient in any program designed to reduce the spread of this life-threatening infection. It also must be continuing, current and targeted for specified audiences.

STATEMENT

J. JARRETT CLINTON, M.D.

DEPUTY ASSISTANT SECRETARY OF DEFENSE
(PROFESSIONAL AFFAIRS AND QUALITY ASSURANCE)
OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

HUMAN IMMUNODEFICIENCY VIRUS

before the

Committee on Veterans' Affairs
United States Senate
100th Congress

June 24, 1987
9:30 a.m.

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

It is my pleasure to appear before you today to discuss the Department of Defense policy on Human Immunodeficiency Virus (HIV). First, I will provide an overview of the current status of our program including serologic test results, medical evaluation program, research initiatives, and educational efforts. I will then review the revised DoD policy on HIV/AIDS issued by Secretary Weinberger on April 20, 1987.

CURRENT STATUS OF PROGRAM

Results of Testing

The Department of Defense recruit applicant screening program began in October 1985. As of March 1987, the Department has screened more than 958,600 civilian recruit applicants with 1454 individuals identified with serologic evidence of HIV infection. This is an overall antibody prevalence rate of 1.5 per thousand, a rate that has been constant during the testing program. Statistical synopses of this information, including geographic specific prevalence rates, are periodically provided wide dissemination through the U.S Public Health Service's Morbidity and Mortality Weekly Report (the most recent report attached). State specific information is provided quarterly to each state health officer by the Centers for Disease Control.

The Armed Forces Blood Program has screened approximately 306,000 units of blood since October 1985. The Western Blot confirmed antibody positivity rate for the latest quarter, January- March 1987, was 0.3 per thousand units tested. This rate is similar to that reported by the national civilian blood collection agencies.

Prior to implementation of the HIV serologic case identification program, approximately 195 clinical cases of Acquired Immune Deficiency Syndrome (AIDS) and/or AIDS Related Complex (ARC) were diagnosed in active duty military personnel. The distribution of AIDS and ARC cases diagnosed in active duty personnel for 1982-1985 is:

YEAR	AIDS	AIDS RELATED COMPLEX
1982	1	0
1983	17	7
1984	28	17
1985	70	55
TOTAL	116	79

The active force screening program began in late 1985 and was fully implemented in 1986. As of this spring, more than 1.7 million active force personnel (Army- 750,000; Navy- 474,000; Marine Corps- 161,000; Air Force- 333,000) have been tested, with

2777 identified with serologic evidence of HIV infection. This is an antibody positivity rate of about 1.6 per thousand individuals screened (Navy = 0.24%; Marines = 0.10%; Army = 0.14%; Air Force = 0.12%).

Epidemiological analysis accomplished by medical researchers at the Walter Reed Army Institute of Research is providing the Department with preliminary information regarding the demographic characteristics of HIV infection among a cohort of active duty Army personnel (example attached). Preliminary analysis of data from the other Services suggests that their results are similar. Ongoing epidemiological research will provide valuable data on which to project the potential inpact of this illness on our military forces.

At this time we are unable to project with reasonable accuracy the incidence or prevalence of HIV infection over the next five years. Because all new recruits are not exposed to HIV at the time of entry and an aggressive information and education program has been instituted, we believe that the rate for HIV and AIDS will not escalate rapidly.

Each individual confirmed to be HIV infected receives extensive evaluation, psychological support, and treatment at select Service medical treatment facilities. Each patient's stage of infection is categorized in accordance with a clinical research protocol initially developed by Walter Reed Army

Institute of Research. The Military Departments have reported that approximately 264 of these patients have clinical manifestations of infection which very roughly can be equated to syndromes such as pre-AIDS and ARC, and an additional 66 patients were frank AIDS cases. Following are data which demonstrate the initial stages of infection of those identified as HIV positive who thus far have been medically evaluated:

	ALL DoD		NAVY/MC		ARMY		AIR FORCE	
DoD Clinical Category	#	%	#	%	#	%	#	%
Category One	971	(57)	672	(82)	174	(28)	125	(49)
Category Two	398	(23)	85	(10)	256	(41)	57	(23)
Category Three	130	(8)	27	(3)	86	(14)	17	(7)
Category Four	54	(3)	10	(1)	36	(6)	8	(3)
Category Five	80	(5)	13	(2)	44	(7)	23	(9)
Category Six	66	(4)	16	(2)	28	(4)	22	(9)
TOTAL CASES	1699	(100)	823	(100)	624	(100)	252	(100)

Individuals in category 1 have serologic evidence of infection but no other abnormal clinical findings. Individuals classified in category 2 usually have chronic lymphadenopathy but all other clinical parameters are essentially normal. Categories 3 and above are indicative of an increasing impairment of the immune system. Previous clinical designations such as 'pre-AIDS' or ARC can be roughly compared to categories 3-5. Category 6 is characterized by the occurrence of an opportunistic infection and is equivalent to AIDS. These data indicate that only a small number of our active duty personnel infected with the AIDS virus currently require inpatient care. HIV infected patients will return annually to Service medical centers for re-evaluation and reclassfication. A clearer picture of the potential for progressive disease due to HIV infection will emerge after the second round of clinical evaluations is accomplished. How many infected individuals who will progress to stages requiring inpatient care is still a matter of scientific debate, with estimates ranging from 30-90 percent.

The Department of Defense medical cost accounting system does not provide inpatient and outpatient costs by diagnosis.

Research Efforts

The Department's research efforts are now well established. Program guidance directs research on diagnosis and patient evaluation, epidemiology in military relevant populations, and the natural history of infection and response to military hazards. While basic research on drug and vaccine development has been restricted, the testing of candidate drugs and vaccines in cooperation with the national program was encouraged. The Army, as lead agency for infectious disease research within DoD, has the responsibility for administering the research program. DoD received $37.8M in FY 86; $21.8M was appropriated for FY 87. The President's Budget contains $5M for FY 88 and $12M for FY 89. Department of Defense financed inhouse research proposals and extramural contracts receive both a scientific merit review by a civilian expert panel, and a military relevance review by

Department program managers. During four review cycles over 120 proposals have been reviewed, 56 were approved for scientific merit and 41 were judged to have military relevance and were approved for funding. One third of the proposals are in Federal laboratories (Army, Navy, Air Force, Uniformed Services University of Health Sciences, Armed Forces Institute of Pathology, National Institutes of Health, Centers for Disease Control, and VA (detailed below). Extensive collaboration with the Public Health Service and other Federal agencies has been maintained. This includes a DoD/VA Joint Committee on Continuity of Care and Research.

DoD FUNDED RESEARCH BY VA INVESTIGATORS

W. W. Tourtellotte	$1,052,000
HIV Infection of the Central Nervous System - a longitudinal clinical study characterizing the neuropathology of HIV infection and the associated aberrant immune response.	
Michale Simberkoff	$1,405,000
Treatement of AIDS and AIDS Related Complex - Phase 3 drug testing which is currently examining the use of AZT in AIDS patients at 4 VA medical centers.	

We believe that the Department of Defense program is making a significant contribution to the understanding of AIDS and HIV infection in the military. Examples of information now available include a better understanding of the potential for HIV infection in the population from which we draw our recruits, the discovery of a genetically engineered antigen that may replace the expensive Western blot procedure as the confirmatory test in serological testing, new labeled probe techniques for identifying virus in tissues, and information on the worldwide epidemiology of HIV infection.

Information & Education

The DoD HIV/AIDS Information and Education effort is also well established. A Departmental coordinating committee provides a forum for information sharing among the Services, reviews and rates print and audiovisual materials for use within the Department, recommends materials for joint-interest purchase, and coordinates requests for materials from national and voluntary organizations. The Department has centrally funded $153,000 for publications and approximately $71,500 for films. The Services have spent approximately $137,800 for educational films. In addition, the Department has made extensive use of materials available from other federal agencies and voluntary organizations at no cost to DoD. Several education, information and motivation materials have been obtained from the Public Health Service. Print materials include: "Surgeon General's Report on Acquired Immune Deficiency Syndrome" (3-4 thousand were provided free and an order for 470,300 has been requested for purchase); "Facts

About AIDS"; "Coping with AIDS"; and, several leaflets coproduced by the Public Health Service and the American Red Cross ("AIDS, Sex, and You", "Facts About AIDS and Drug Abuse", etc.). In addition, information published in the Morbidity and Mortality Weekly Report is furnished to military medical personnel. Master copies of the following videotapes have been provided to the Department of Defense from the Public Health Service: "AIDS: Fears and Facts" for general audience, "What If the Patient Has AIDS?" for health care workers, and "AIDS and Your Job" for policemen, firemen, and other emergency workers. The Department purchased 1.2 million copies of the booklet, "What You Should Know About HTLV-III/AIDS", for the general military audience. Numerous articles about HIV/AIDS have been prepared by the Armed Forces Information Service and distributed to military editors via the "Presspack" and in the "Defense Billboard". A commercial film, "Facts Over Fears", for general audiences was purchased and has been distributed to Service Audiovisual Distribution Centers. The American Red Cross film, "Beyond Fear", has been used by the Services and we have requested a master to reproduce copies for our audiovisual centers. Public Service television spots have also been reproduced for use overseas. The individual Services have developed briefing packets and purchased materials for specific audiences.

POLICY DIRECTION

The original guidance for this program was issued in October 1985. After a thorough policy review process in the fall of 1986, a revised policy was issued by the Secretary on 20 April 1987. The essential elements of the Department's policy are presented below.

Accession

Individuals with serologic evidence of HIV infection (Food and Drug Administration approved enzyme immunoassay (EIA) serologic test and, if positive, a positive immunoelectrophoresis test (Western blot)), are not eligible for appointment or enlistment for military service. For other categories of personnel (ROTC, Service Academy, Reserve Components), the general guideline is that those individuals with serologic evidence of HIV infection who are required to meet accession medical fitness standards in order be appointed to a new component are not eligible to do so.

Disease Surveillance-Military Personnel

Active duty and reserve component military personnel are screened for serologic evidence of HIV infection (Food and Drug Administration approved enzyme immunoassay (EIA) serologic test and, if positive, a positive immunoelectrophoresis test (Western blot)). Initial testing and periodic retesting is accomplished in the following priority order: military personnel serving in, subject to deployment, or pending assignment to overseas stations; select groups in the medical setting such as, individuals presenting to sexually transmitted disease clinics; and, all remaining military personnel in conjunction with routinely scheduled periodic physical examinations.

Disease Surveillance-All Beneficiaries

For all beneficiaries of the military health care system, a voluntary HIV serologic screening program is provided in accordance with published recommendations of the U.S. Public Health Service and as indicated by standard medical practice. For example, HIV serologic screening can be offered to beneficiaries presenting at sexually transmitted disease clinics, alcohol and drug rehabilitation units, and prenatal clinics.

In addition, health care beneficiaries concerned about whether they have been exposed to HIV are encouraged to consult with local DoD medical personnel. As is the procedure for other problems, such as other sexually transmitted diseases, the beneficiary may obtain an appointment and discuss his or her concerns directly with the physician. The appropriate supporting tests, including laboratory evaluation, are determined by the physician.

Mandatory screening of civilian employees or dependents for serologic evidence of HIV infection prior to military sponsorship overseas is not presently authorized. Policies involving screening of civilians as an integral part of a complete medical examination prior to military sponsorship overseas, and administration of family members or civilian employees proposed for military sponsorship or under military sponsorship overseas who develop clinical manifestations of HIV infection or serologic evidence of HIV infection will be developed, as necessary, by the Assistant Secretary of Defense (Force Management and Personnel) in consultation with the Assistant Secretary of Defense (Health Affairs) and the General Counsel.

Medical Assessment and Preventive Medicine Intervention

The medical assessment of each individual with serologic evidence of HIV infection seen at a military medical treatment facility includes an epidemiological assessment of the potential transmission of HIV to other persons at risk of infection including sexual and other intimate contacts, and family of the patient. This information is vital to provide appropriate preventive medicine counseling and to the continued development of scientifically based information regarding the natural history and transmission patterns of HIV. Therefore, the occurrence of HIV infection or serologic evidence of HIV infection is not used as a basis for any disciplinary action against an individual.

Each military medical service conducts an ongoing clinical evaluation of each active duty military member with serologic evidence of HIV infection at least annually. Additionally, each military medical service conducts longitudinal clinical evaluations of active duty military personnel with serologic evidence of HIV infection and prepares internal reports to facilitate timely review and reassessment of current policy guidelines.

All military medical treatment organizations are required to notify the cognizant military health authority whenever a diagnosis of HIV infection is made or whenever laboratory examination of any specimen yields evidence indicative of infection with HIV. Upon notification, the cognizant military health authority undertakes preventive medicine intervention including counseling of the individual and others at risk of infection regarding transmission of the virus, coordination with military and civilian blood bank organizations to trace back possible exposure through blood transfusion or donation of infected blood, and referral of appropriate case contact information to the cognizant military or civilian health authority. All individuals with serologic evidence of HIV infection who are military health care beneficiaries are counseled by a physician or designated health care provider regarding the significance of a positive antibody test. They are advised as to the mode of transmission of this virus, the appropriate precautions and personal hygiene measures required to minimize transmission through sexual activities and/or intimate contact with blood or blood products, and of the need to advise any past sexual partners of their infection. Women are advised of the risk of perinatal transmission during past, current and future pregnancies. The beneficiary is informed that he or she is ineligible to donate blood and will be placed on a permanent donor deferral list.

Epidemiological investigation attempts to determine potential contacts of the patient with serologic or other laboratory or clinical evidence of HIV infection. The patient is informed of the importance of case contact notification to interrupt disease transmission and is informed that contacts will be advised of their potential exposure to HIV. Those individuals determined to be at risk who are identified and who are eligible for health care in the military medical system are notified. Military members identified to be at risk are counseled and tested for serologic evidence of HIV infection. Other beneficiaries, such as retirees and family members, identified to be at risk are informed of their risk and offered serologic testing, clinical evaluation, and counseling. The names of individuals identified to be at risk who are not eligible for military health care are provided to local civilian health authorities unless prohibited by the appropriate state or host nation civilian health authority. Anonymity of the HIV index case is maintained unless reporting is required by the health jurisdiction. Communicable disease reporting procedures of civil authorities are followed to the extent consistent with DoD guidance through liaison between the military public health jurisdiction and the appropriate local, state, territorial, federal, or host-nation health jurisdiction.

Due to the high priority assigned to the continued medical evaluation of military personnel with serologic evidence of HIV infection, such individuals are assigned within the United States. Additionally, the Secretaries of the Military Departments, in order to protect the health and safety of military personnel with serologic evidence of HIV infection and of other military personnel, may limit assignment of such individuals with respect to the nature and location of the duties performed in accordance with operational requirements.

Health Education

The Assistant Secretary of Defense (Health Affairs) is responsible for coordinating the overall policy guidance for the HIV/AIDS education and information program. The Military medical departments are responsible for ensuring that appropriate preventive medicine counseling is given to individual patients and for providing public health education materials to its beneficiary population. As elaborated previously, a comprehensive, integrated, and coordinated program is ongoing. Additionally, prophylactic devices, such as condoms and spermicides, are readily available at military post and base exchanges and ship stores. Sale of these items in military commissaries is also being considered.

Retention and Separation

Active duty personnel with serologic evidence of HIV infection are referred for a medical evaluation for documentation of fitness for continued service in the same manner as personnel with other progressive illnesses. Evaluation is conducted in accordance with a standardized clinical protocol. Individuals with serologic evidence of HIV infection who show no evidence of clinical illness or other indication of immunologic or neurologic impairment related to HIV infection are not separated solely on the basis of serologic evidence of HIV infection.

Reserve component members with serologic evidence of HIV infection are ineligible for extended active duty (duty for a period of more than 30 days) except under conditions of mobilization. Reserve component members who are not on extended active duty (duty for a period of more than 30 days) or who are not on extended full-time National Guard duty and who show serologic evidence of HIV infection are transferred to the Standby Reserve only if they cannot be utilized in the Selected Reserve.

Military personnel who are infected with HIV and who are determined to be unfit for further duty are given a medical retirement or are medically separated.

Military personnel with serologic evidence of HIV infection who are found not to have complied with lawfully ordered preventive medicine procedures for individual patients are subject to appropriate administrative and disciplinary action which may include separation.

Safety of the Blood Supply

Armed Services Blood Program Office policies, Food and Drug Administration guidelines, and accreditation requirements of the American Association of Blood Banks are followed by the Military Departments and Unified and Specified Commands and by civilian blood agencies collecting blood on military installations.

Limitations on the Use of Information

Information obtained from a service member during or as a result of an epidemiologic assessment interview may not be used against the service member in a court martial; nonjudicial punishment; involuntary separation (other than for medical reasons); administrative or punitive reduction in grade; denial of promotion; an unfavorable entry in a personnel record; a bar to reenlistment; and any other action considered by the Secretary concerned to be an adverse personnel action.

Results obtained from laboratory tests for HIV may not be used as the basis for separation of the service member except for a separation based upon physical disability or as specifically authorized by DoD policy. The limitations on use of information obtained from a member do not apply to: the introduction of evidence for impeachment or rebuttal purposes in any proceeding in which the evidence of drug abuse or relevant sexual activity (or lack thereof) has been first introduced by the service member or to disciplinary or other action based on independently derived evidence; or, nonadverse personnel actions such as reassignment, disqualification (temporary or permanent) from a personnel reliability program, denial, suspension, or revocation of a security clearance, suspension or termination of access to classified information, and, removal (temporary or permanent) from flight status or other duties requiring a high degree of stability or alertness such as explosive ordnance disposal or deep-sea diving.

CONCLUSION

The initial DoD policy on HIV focused on protecting the health of the individual service member. The Department was concerned about possible untoward effects of multiple live virus vaccines on the individual and the potential transmission of the virus under battlefield or contingency conditions to other individuals. The revised policy reiterates this paramount concern and more fully addresses the Department's comprehensive, multifaceted approach to prevention and control of this epidemic that challenges the health of our nation. The target of our attack is the Human Immunodeficiency Virus. Our concern is the health of our fighting force and the health of our other health care beneficiaries. Our program is based on sound preventive medicine and public health concepts and is fully integrated with other national initiatives.

The Department of Defense has developed extensive coordination and collaboration links with all major agencies of the U.S. Public Health Service, the Federal Coordinating Committee on AIDS Information, Education and Risk Reduction, and has co-chaired the Department of Defense-Veterans Administration Joint Committee on Continuity of Care and Research. These communication channels have facilitated program development and ensured coordination of responsibilities and functions.

This concludes my testimony. I would be pleased to respond to any questions.

CENTERS FOR DISEASE CONTROL

May 15, 1987 / Vol. 36 / No. 18

MMWR

MORBIDITY AND MORTALITY WEEKLY REPORT

273 Trends in Human Immunodeficiency Virus Infection Among Civilian Applicants for Military Service — United States, October 1985-December 1986
281 Pertussis Immunization, Family History of Convulsions and Use of Antipyretics — Supplementary ACIP Statement
282 Organic Solvents in the Workplace

Epidemiologic Notes and Reports

Trends in Human Immunodeficiency Virus Infection Among Civilian Applicants for Military Service — United States, October 1985-December 1986

Since October 1985, the U.S. Department of Defense has routinely tested civilian applicants for serologic evidence of infection with human immunodeficiency virus (HIV) as part of their preinduction medical evaluation (*1*). Results from the first 6 months of testing have been reported previously (*2,3*). Results for the first 15 months provide the opportunity to observe trends of infection in this population.

Between October 1985 and December 1986, 789,578 civilian applicants for military service were screened. Of these, 1,186 were confirmed as HIV-antibody positive by enzyme immunoassay and Western blot immunoelectrophoresis, for an overall rate of 1.5/1,000 individuals tested. Seroprevalence per 1,000 varied by age, sex, race and ethnicity, and region of residence. By age, it was 0.6 for 17-20 year-olds, 2.5 for 21-25 year-olds, and 4.1 for those ≥ 26 years of age. By sex, it was 1.6 for males and 0.6 for females. By race and ethnicity, seroprevalence per 1,000 was 0.8 for whites, 4.1 for blacks, 2.3 for Hispanics, 1.0 for American Indians or Alaskan Natives and Asian or Pacific Islanders. Table 1 shows the seroprevalence among civilian applicants by region of residence.

TABLE 1. Prevalence of HIV antibody* among civilian applicants for military service, by age group and region of residence — October 1985-December 1986

	Age Group (Years)			
Region†	**17-20**	**21-25**	**≥26**	**All Ages**
New England	0.4	1.0	3.8	0.9
Middle Atlantic	0.7	4.6	10.0	2.9
EN Central	0.4	1.8	1.9	0.9
WN Central	0.2	1.0	1.8	0.6
South Atlantic	0.9	3.4	5.4	2.1
ES Central	0.4	1.9	1.3	0.9
WS Central	0.6	2.7	3.0	1.6
Mountain	0.3	1.5	1.9	0.9
Pacific	0.8	1.5	4.0	1.5
US Territories	1.6	6.3	12.3	5.8
All Regions	0.6	2.5	4.1	1.5

*Repeatedly reactive enzyme-linked immunosorbent assay (ELISA) test confirmed by Western blot immunoelectrophoresis; reported as the number of antibody-positive applicants per 1,000 tested

†Defined in notifiable diseases table (Table III)

HIV Infection – Continued

During the 15-month observation period, the seroprevalence did not change significantly, either in the aggregate or when analyzed by age, sex, race and ethnicity (Figure 1), or geographic region. However, seroprevalence among white males showed a small but significant decline of 0.02/1,000 applicants tested per month ($p = 0.016$ by Chi Square test for trends in proportions using a logistic regression linear model).

Reported by: Health Studies Task Force, Office of the Assistant Secretary of Defense (Health Affairs), US Dept of Defense, Washington, DC. Div of Preventive Medicine and Div of Communicable Diseases and Immunology, Walter Reed Army Institute of Research, Washington, DC. Surveillance and Evaluation Br, AIDS Program, Center for Infectious Diseases, CDC.

Editorial Note: AIDS cases reported to CDC continue to increase*. However, because of the lengthy incubation period of AIDS (*4*), these cases represent infection occurring at least several years prior to the report of disease. There has been little information to indicate current trends in HIV infection. Analysis of the results of the testing of civilian applicants thus far basically shows neither an increase nor a decrease in infection level for the group as a whole or for individual subgroups. The significance of this apparent absence of change in antibody prevalence during the 15-month period studied is not yet clear.

Volunteers for military service, who are verbally screened by the recruiting official prior to arrival at the medical evaluation center, are not fully representative of the overall population in that they underrepresent the three groups in the United States with the highest prevalence of HIV infection[†]. Moreover, applicants do not equally represent all socioeconomic and demographic groups in the population. A growing awareness of the military serologic screening program may have increased self-deferral by persons who are HIV-antibody positive or who feel they may have been exposed to the virus. If so, this could have masked an increased frequency of infection in the population from which the applicants are drawn.

Monitoring trends in infection among civilian applicants for military service as well as among blood donors[§] remains important. It is also critical to compare trends in infection among these volunteer groups with similar trends among groups not affected by self-selection bias. One such surveillance approach, in which anonymously tested sample populations without AIDS-like disease are monitored at participating hospitals, has been initiated recently by CDC. Trends in exposure risks among seropositive individuals should also be monitored to assess possible changes in the relative frequency of the various modes of transmission. Follow-up interviews of a small number of seropositive applicants have found a high proportion with typical risk exposures for AIDS (*5*). CDC is collaborating with the U.S. Department of Defense, the National Cancer Institute of the National Institutes of Health, and certain state and local health departments to develop a systematic follow-up evaluation of seropositive civilian applicants in selected cities and states.

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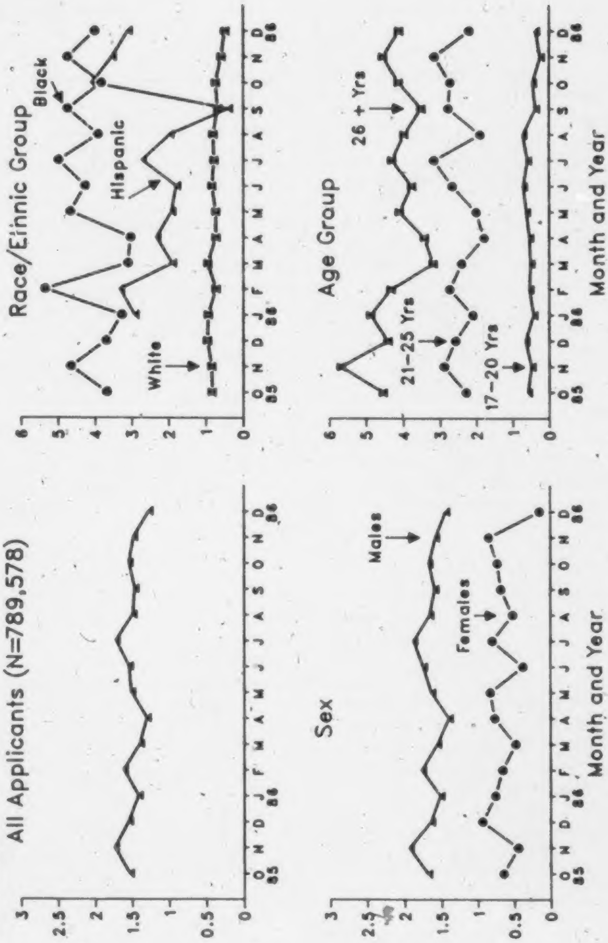
*An average of 38.3 AIDS cases per day were reported for the period October-December 1986, compared with an average of 26.3 per day for the period October-December 1985.

[†] Active intravenous drug abusers, homosexual men, and hemophiliacs.

[§] Long-term data are not yet available for this group.

HIV Infection – Continued

JRE 1. Human immunodeficiency virus antibody among civilian applicants*, by month — United States, October 5-December 1986



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*U.S. Department of Defense data

HIV Infection – Continued

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5. Stoneburner RL, Chiasson MA, Solomon K, Rosenthal S. Risk factors in military recruits positive for HIV antibody [Letter]. N Engl J Med 1986;315:1355.

TABLE I. Summary – cases specified notifiable diseases, United States

Disease	18th Week Ending			Cumulative, 18th Week Ending		
	May 9, 1987	May 3, 1986	Median 1982-1986	May 9, 1987	May 3, 1986	Median 1982-1986
Acquired Immunodeficiency Syndrome (AIDS)	303	203	N	6,494	4,307	N
Aseptic meningitis	75	67	75	1,515	1,497	1,406
Encephalitis: Primary (arthropod-borne & unspec)	13	6	18	262	271	318
Post-infectious	1	4	3	20	37	35
Gonorrhea: Civilian	12,549	14,517	15,686	268,252	287,371	287,371
Military	364	149	384	5,905	5,255	7,375
Hepatitis: Type A	439	300	370	8,444	7,619	7,619
Type B	439	493	468	8,540	8,688	8,450
Non A, Non B	53	61	N	1,028	1,179	N
Unspecified	60	88	114	1,144	1,705	1,812
Legionellosis	7	6	N	250	205	N
Leprosy	-	7	7	72	101	97
Malaria	9	18	18	226	249	247
Measles: Total*	142	215	81	1,276	2,526	1,084
Indigenous	133	188	N	1,100	2,426	N
Imported	9	27	N	176	96	N
Meningococcal infections: Total	38	52	58	1,208	1,139	1,209
Civilian	38	52	58	1,207	1,137	1,198
Military	-	-	-	1	2	4
Mumps	349	75	91	6,665	1,227	1,445
Pertussis	12	47	40	584	882	618
Rubella (German measles)	12	4	22	118	177	257
Syphilis (Primary & Secondary): Civilian	531	545	545	11,219	8,914	9,819
Military	1	-	4	68	79	117
Toxic Shock syndrome	1	2	N	104	123	N
Tuberculosis	327	459	441	6,720	6,790	6,957
Tularemia	1	-	4	35	21	33
Typhoid Fever	10	6	6	94	81	117
Typhus fever, tick-borne (RMSF)	7	3	15	28	30	53
Rabies, animal	100	132	132	1,664	1,906	1,906

TABLE II. Notifiable diseases of low frequency, United States

	Cum. 1987		Cum. 1987
Anthrax	-	Leptospirosis	8
Botulism: Foodborne (Ohio 1, Calif 1)	3	Plague	2
Infant	18	Poliomyelitis, Paralytic	-
Other	-	Psittacosis (Maine 1)	27
Brucellosis (Ohio 1, Tex 1)	28	Rabies, human	-
Cholera	-	Tetanus	9
Congenital rubella syndrome	3	Trichinosis	11
Congenital syphilis, ages < 1 year	-	Typhus fever, flea-borne (endemic, murine) (N Y City 1)	8
Diphtheria	1		

*Five of the 142 reported cases for this week were imported from a foreign country or can be directly traceable to a known internationally imported case within two generations.

US ARMY HIV DATA SYSTEMS (USAHDS) SUMMARY REPORT

DIVISION OF PREVENTIVE MEDICINE
WALTER REED ARMY INSTITUTE OF RESEARCH
WASHINGTON, D.C. 20307-5100

COMMERCIAL (202) 576-3517
AUTOVON 291-3517

Vol.1 Issue 1

Data as of: 6 April 1987

TOTAL HIV POSITIVES BY MEDICAL CENTERS

MTF STATUS

FREQUENCY	AD ARMY	RESERVE	NAT. GUARD	OTHER AD	OTHERS	TOTAL
BROOKE AMC	79	1	6	10	17	113
EISENHOWER AMC	162	5	22	26	25	240
FITZSIMONS AMC	86	3	12	9	39	149
LETTERMAN AMC	56	2	12	8	21	99
MADIGAN AMC	25	1	0	1	5	32
TRIPLER AMC	33	0	0	14	24	71
BEAUMONT AMC	43	0	3	1	13	61
WALTER REED AMC	258	6	15	24	74	377
EUROPE	91	1	0	2	11	105
OTHER/UNKNOWN	42	7	10	9	5	73
TOTAL	875	26	80	105	234	1320

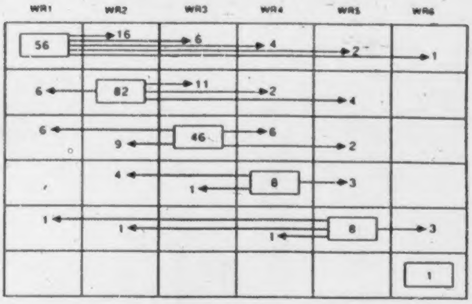
CLINICAL EVALUATIONS BY MEDICAL CENTERS

MTF STATUS

FREQUENCY	[illegible]	WR1	WR2	WR3	WR4	WR5	WR6	* WR7	TOTAL
BROOKE AMC	0	46	7	3	2	7	3	0	68
EISENHOWER AMC	10	60	73	37	13	4	1	0	198
FITZSIMONS AMC	6	24	74	8	4	5	5	1	127
LETTERMAN AMC	2	21	24	10	7	10	1	0	75
MADIGAN AMC	0	10	5	5	1	1	0	0	22
TRIPLER AMC	14	17	8	2	3	2	1	0	47
BEAUMONT AMC	1	13	3	10	3	0	0	0	30
WALTER REED AMC	3	21	102	30	8	11	7	0	188
EUROPE	10	13	33	10	8	6	1	0	76
OTHER/UNKNOWN	1	2	5	1	0	1	0	0	10
TOTAL	47	227	333	130	46	47	19	1	880

*[illegible] REPORTED DEATHS

WALTER REED CLINICAL STAGES
USAHDS



Br ficates initial stage of individuals staged more than (ines indicate most recent stage if different from i .tage

Reclassifications reflect variability in parameters that define stages, as well as clinical progression. Reclassifications to lower stages should not be interpreted as documenting clinical improvement.

WALTER REED CLINICAL STAGES
RECLASSIFICATIONS TO LOWER STAGE AND HIGHER STAGE
AFTER FOLLOW-UP
USAHDS

Numbers indicate proportions of individuals, by initial stage, who have been restaged to higher (upper portions) or lower (lower portion) clinical stages - by varying lengths of follow-up.

Reclassifications reflect variability in parameters that define stages, as well as clinical progression. sifications to lower stages should not be ited as documenting clinical improvement.

INITIAL STAGE	< 3 MONTHS		3-6 MONTHS		> 6 MONTHS		TOTAL	
WR1	0/3	0%	10/18	56%	19/35	54%	29/56	50%
	-	-	-	-	-	-	-	-
WR2	3/7	43%	3/27	11%	11/48	23%	17/82	21%
	0/7	0%	4/27	15%	2/48	4%	6/82	7%
WR3	2/15	13%	1/10	10%	5/21	24%	8/46	17%
	5/15	33%	7/10	40%	6/21	29%	15/46	33%
WR4	1/2	50%	0/1	0%	2/5	40%	3/8	38%
	1/2	50%	1/1	100%	3/5	60%	5/8	62%
WR5	1/3	33%	1/2	50%	1/3	33%	3/8	38%
	2/3	67%	0/2	0%	1/3	33%	3/8	38%
WR6	0/0	-	0/0	-	0/1	0%	0/1	0%
	0/0	-	0/0	-	0/1	0%	0/1	0%
TOTAL	7/30	23%	14/58	24%	38/113	34%	60/201	30%
	8/27	30%	9/40	23%	12/78	15%	29/145	20%

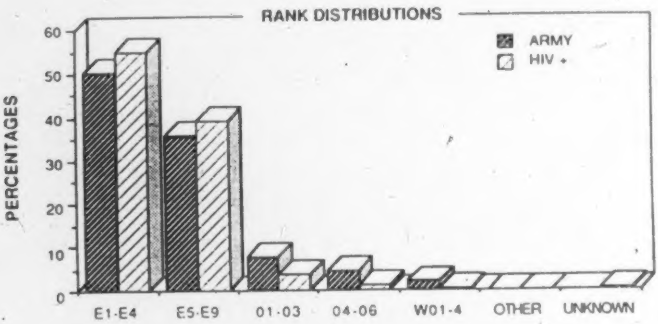
HIGHEST REPORTED STAGE (ALL SOURCES)

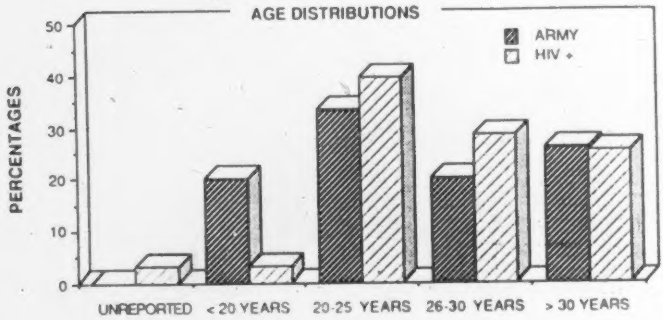
For each antibody positive individual, the highest reported clinical stage (regardless of the number of staging assessments) is indicated. Sources of these data include clinical evaluation forms, Med-16's, and discharge diagnoses (i.e. IPDS records).

NOTE: Specific parameters must persist for 3 months or greater for accurate staging. These include lymphadenopathy, quantitative depletion of T-helper cells and defects in delayed hypersensitivity. Only stages WR0, WR1, and WR6 can be definitively assigned after a single visit. Stages WR2, WR3, WR4 and WR5 require demonstration of persistent defects of parameters. Use of an asterisk (*) is recommended at the initial staging in these instances to indicate the stage is tentative. When persistence is demonstrated, the asterisk is deleted and classification is complete. If persistence is not demonstrated, the asterisk is also removed and the is classified at the earliest stages at which essential criteria are After classification has been confirmed by follow-up, reclassification to an earlier stage cannot occur by definition. Individual parameters (T-helper cell, adenopathy, delayed hypersensitivity) may vary to levels consistent with an earlier stage without reclassification to an earlier stage. This variability will be assessed independently.

HIGHEST STG	FREQUENCY	PERCENT	CUMULATIVE FREQUENCY	CUMULATIVE PERCENT
NO STAGE REPORTED	236	27.1	236	27.1
WR1	177	20.3	413	47.4
WR2	274	31.4	687	78.8
WR3	89	10.2	776	89.0
WR4	37	4.2	813	93.2
WR5	41	4.7	854	97.9
WR6	15	1.7	869	99.7
WR7	3	0.3	872	100.0

Eight hundred seventy five HIV positive active duty Army individuals have been identified as of this date. The figures below represent distributions of these individuals by age, rank and sex. Overall distributions of age, rank and sex of the Army are also represented. It is important to note that individuals tested to date may not accurately represent the total Army population; and specific conclusions should not be made m these data.





DISTRIBUTION BY SEX

SEX	ARMY	HIV +
MALE	90.1%	93.8%
FEMALE	9.9%	5.3%

USAHDS is operated by the Department of Epidemiology, Division of Preventive Medicine, Walter Reed Army Institute of Research for the Office of the Surgeon General.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

STATEMENT OF
JAMES W. CURRAN, M.D.
DIRECTOR, AIDS PROGRAM
CENTER FOR INFECTIOUS DISEASES
CENTERS FOR DISEASE CONTROL
PUBLIC HEALTH SERVICE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
U.S. SENATE

JUNE 24, 1987

Mr. Chairman and Members of Committee:

I am pleased to have this opportunity to represent the Centers for Disease Control (CDC) and to share our knowledge about the nature of the acquired immunodeficiency syndrome (AIDS).

The AIDS epidemic continues to grow. More than 37,000 cases of AIDS have been reported to date; and more than 21,000 of these patients have already died. The President has declared AIDS the number one public health enemy.

AIDS cases have been reported from all 50 States, the District of Columbia, Puerto Rico and other territories. New York State (29 percent of the US total) and California (23 percent) represent the two States reporting the highest number of cases.

Patient characteristics indicate that 93 percent of AIDS cases are male and 89 percent are between 20 and 49 years of age. A breakdown by race includes white (60 percent), black (25 percent), hispanic (14 percent) and other (1 percent). Primary transmission categories include homosexual/bisexual males (66 percent), intravenous (IV) drug abusers, (17 percent) and homosexual males who are also IV drug abusers (8 percent). The remaining categories include hemophilia (1 percent), heterosexual contact (4 percent), transfusion related (2 percent) and undetermined (3 percent). We are unable to provide a similar breakdown for "AIDS Related Complex" (ARC) patients, since this information is not routinely collected by most State health departments.

The completeness of reporting of AIDS cases that meet the CDC definition is estimated to be approximately 90 percent, based on validation studies in five major cities; this is extraordinarily high when compared to other diseases, where typically 10-25 percent of cases are reported. "AIDS Related Complex" (ARC) is a term variably used to refer to seriously ill persons without "definite AIDS" as well as a much larger number of persons with only mild signs or symptoms associated with HIV infection. ARC is not generally a required reportable condition in most States since mild disease typically is poorly ascertained and reported. For example, two county health departments which currently conduct surveillance of ARC and generalized lymphadenopathy receive fewer reports of these conditions than AIDS case reports indicating severe underreporting of the milder disease forms. Based on cohort studies such as the one in San Francisco, where the number of ARC cases initially seen was 8 times the number of AIDS cases, ARC is expected to far outnumber AIDS among groups of infected persons. It is currently estimated that the total prevalence number of HIV infection, including both symptomatic and asymptomatic individuals, in the United States is between 1 and 1-1/2 million individuals.

It is estimated that by the end of 1991, the cumulative total of AIDS cases in the United States will reach 270,000 and result in nearly 180,000 deaths. The majority of cases in 1991 will continue to be among homosexual and bisexual men because many of these individuals are already infected. Other patient groups are essentially expected to remain the same as today except a proportional increase is expected in heterosexual contact cases.

Although the majority of cases continue to occur among homosexual and bisexual men and intravenous (IV) drug abusers, the infection is also being heterosexually spread by sexually active individuals who do not abuse IV drugs intravenously. Infected mothers are also transmitting infection to their newborn infants. Fourteen hundred cases of heterosexual transmission and more than 500 cases among children are related to contact with persons with AIDS, at risk for AIDS, or are individuals born in countries in which heterosexual transmission is believed to play a major role.

We know that the overwhelming majority of cases continue to occur in populations known to be at risk. Although the number of cases being transmitted heterosexually is increasing, the individuals most affected are sex partners of bisexual men and IV drug abusers—most often black and Hispanic women.

We are gradually learning more about the natural history of HIV infection. In the San Francisco City Clinic Cohort study of homosexual men with HIV infection, the average annual incidence of AIDS was shown to increase over time. After 2 years of infection, only 1 percent of the men had progressed to AIDS. The rate increased to 5 percent after 3 years of infection, 10 percent after 4 years, 15 percent after 5 years, 24 percent after 6 years, and 30 percent after 7 years. Limited data in trends of new HIV infections over time in cohorts of homosexual men have shown declining rates of new infection over the last two to three years. The percent of military recruit applicants and first time blood donors testing positive has not increased significantly in 15 to 18 months of ongoing testing; however, trends in these groups may not accurately reflect trends in the general population.

State and local health departments have reported to CDC a total of 999 AIDS patients diagnosed at and reported by Veteran's Administration Medical Centers since 1981. A much larger number of reported patients with AIDS have received care at VA Centers, since most patients have multiple hospitalizations during the course of their illness. Only the initial hospital diagnosing AIDS is reported to CDC. Of this total, 997 were male and 2 were female. Other VA patient characteristics reveal that 46 percent were white, 39 percent black, and 14 percent hispanic. Seventy-one percent of total VA reported cases were between the ages of 25 and 44. The highest concentration of patients were from the mid-Atlantic States (45 percent). Risk factors reveal that 49 percent are homosexual or bisexual men, 34 percent are IV drug users; 10 percent are homosexual men who use IV drugs; and the modes of transmission for the remaining 7 percent of cases were heterosexual contact with high-risk individuals, transfusion related or undetermined.

The Department of Health and Human Services has the lead role in our efforts to prevent and control AIDS; however, the problem touches many parts of the Federal Government. The President has approved increased testing for Federal prisoners and immigrants and has requested a review of other Federal programs where routine testing could be done. In addition, HHS is moving rapidly to conduct a nationwide study of the prevalence and incidence of HIV virus in America.

Despite extensive research efforts, there is no vaccine against AIDS, and only one licensed drug with limited proven therapeutic benefit has been developed. Complicating the picture is the fact that infected persons are capable of spreading the virus to others for years before experiencing the signs or symptoms of AIDS. At this time, information and education, aimed at motivating individuals to eliminate high-risk behavior, are the only means we have to prevent the spread of HIV infection—the virus that causes AIDS.

AVAILABILITY OF CLINICAL TRIALS

The National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health currently funds 19 AIDS Treatment Evaluation Units (ATEUs) to conduct collaborative clinical trials of promising therapeutic agents in persons infected with the human immunodeficiency virus. These units are located in 11 States and involve 35 separate medical centers. Currently, 17 protocols are active in the ATEUs with an enrollment of approximately 650 patients. The purpose of the ATEUs is to conduct clinical trials of potentially effective therapies for HIV infection. The intense individual examinations (immunologic, virologic, etc.) required to conduct careful scientific studies limit the number of individuals who can be included. Phase I trials, which determine the safe dose range for a drug and its possible toxicity, usually involve small numbers of patients. Phase II trials may involve up to several hundred patients and provide more information about safety as well as some indication of efficacy. Many of the trials in the ATEUs are Phase I or II studies. A number of Phase III trials are included, however, with one protocol intended to include 1600 patients.

In September of this year, NIAID expects to award cooperative agreements to between 15 and 20 institutions for the establishment of Clinical Studies Groups (CSGs) which will expand the clinical trials efforts into areas of the country where health care providers have not dealt with large numbers of people with AIDS. One goal of the CSG is to encourage clinicians to form a cadre of knowledgeable professionals whose pooled research interests will lead to a better understanding of AIDS. In addition to clinical studies, a CSG may contain a basic research component that will interact with the clinical portion, and/or a component directed toward education and outreach. Although the numbers of patients who will be reached by those groups cannot be determined at this time, this effort will substantially expand access to and availability of clinical trials.

Recently we have made significant changes in the direction and momentum of our efforts to control and prevent AIDS. Eighteen months ago, among our primary concerns were ensuring the safety of our blood supplies and providing alternate testing sites for people who believed they may have been exposed to the AIDS virus. Since then, safeguards have been put in place to make the blood supply safer; the alternate test sites have become counseling and testing programs; and AIDS health education/risk reduction (HE/RR) programs are in place across the Nation.

The report of the PHS meeting in Coolfont, West Virginia, last June and the Surgeon General's Report on AIDS that was issued in October together mark the beginning of a more intense phase in our information and education efforts. The American public has learned a great deal about how they can protect themselves and others from AIDS.

The Department's AIDS information/education efforts, as outlined in the "Information/Education Plan to Prevent and Control AIDS in the United States," are directed toward four target populations: the general public, school and college-aged youth, persons at increased risk or infected, and health workers. Highest priority are those groups at greatest risk of acquiring or transmitting HIV infection. We are providing assistance to every State, supporting health education/risk reduction and counseling and testing activities.

THE PUBLIC

An informed public provides the foundation upon which other information/education programs can build. Individuals need further information on the steps needed to protect their health. Special efforts are needed to provide information through a variety of channels, such as television, radio, press, and advertisements. The program must be closely coordinated and sustained over a long period of time in order to adequately inform the public.

We continue to distribute information to the public. For example, we have distributed hundreds of thousands of copies of the Surgeon General's Report. The national AIDS Hotline is now being operated 24 hours a day, 7 days a week under a contract with the American Social Health Association. An average of 700 calls are answered each day. And, this year we will establish a national AIDS Clearinghouse system and will be contracting with an ad agency to help us design a national public information campaign. We are hoping to have a kickoff for this campaign this coming fall.

SCHOOL AND COLLEGE-AGED YOUTH

In 1987, we are initiating a comprehensive school health education program. A principal feature of the program will be the provision of fiscal support and technical assistance to about 10 State and 12 local education agencies in areas with the highest incidence of AIDS to rapidly implement effective education about AIDS for students and for school-aged youth who do not attend school. The scope and content of these AIDS school health education programs will be determined at the local level with assistance from the health agency. We are coordinating these activities with the Department of Education. Training and demonstration projects will be established in three metropolitan areas and in one State. School officials and teachers from around the country will be able to attend training sessions in order to learn firsthand how to develop and implement effective AIDS education in the schools. In this way we can assist school systems that do not receive direct funding.

To supplement the State and local efforts, we will be working with national organizations to help schools provide effective AIDS education. Through these organizations, we hope to stimulate, reinforce, and assist State and local efforts to reach students, school-aged youth not attending school, college populations, and high-risk Black and Hispanic youth.

To round out our program, we will be undertaking a number of other activities designed to assist the State and local education agencies, such as establishing an annotated computerized bibliography of relevant AIDS educational materials, stimulating private sector development of effective school health education materials, assessing the impact of national, state and local efforts, and establishing a national coalition for AIDS school health education.

PERSONS AT INCREASED RISK OR INFECTED

Prevention and control of AIDS will depend upon successfully interrupting the transmission of the virus among those persons whose behaviors or their circumstances put them and others at risk of infection.

The major element of our efforts to prevent sexually transmitted AIDS is the provision of assistance to States in conducting AIDS prevention programs which include HIV antibody testing, counseling, and health education/risk reduction activities. This year, CDC awarded 58 AIDS Prevention cooperative agreements totaling more than $24 million to States, territories, and selected cities for this purpose.

It is important to view the role of testing and counseling within the context of our overall strategy for preventing the spread of HIV infection. This strategy has two main components designed to alter risk-associated behaviors. The first involves directing AIDS information to the general public and selected subsets of the general public based on the specific needs identified for each. However, a great many people whose behavior puts them at risk for AIDS misperceive their personal risk or deny that risk despite targeted educational campaigns.

Therefore, the second component of the AIDS prevention strategy is designed to reach such high-risk people at a "personal level"—through the provision of educational materials and one-to-one counseling. From the outset, education and counseling were integral to HIV antibody testing because of the potential emotional trauma involved if the test is positive and the need to guide people in making informed decisions and adopting behaviors that would eliminate further transmission.

In mid-1985, funding was provided for 50 testing and counseling projects covering nearly 900 sites through which more than 79,000 people were tested, and many more received AIDS educational materials and heard personal prevention messages from health professionals. Of those tested, about 17 percent were seropositive. Persons who are tested at these sites are self-selected, presumably because they believe themselves to be at increased risk for HIV infection. Therefore the prevalence of seropositivity among these persons would not necessarily be representative of that in the general population.

In 1986, testing sites funded by these projects increased to almost 1,100 through which about 150,000 people were tested. Preliminary reports indicate that nearly 19 percent of those tested were seropositive. Pretest counseling sessions increased 89 percent, and post-test counseling increased by 118 percent in 1986 over 1985.

In March 1986, CDC published recommendations in its Morbidity and Mortality Weekly Report (MMWR) to assist in preventing HIV infection by sexual and IV drug transmission. These recommendations stated that counseling and voluntary serologic testing for HIV antibody should be offered routinely to all persons at increased risk when they present to health care settings. Such facilities included, but were not limited to, sexually transmitted disease (STD) clinics, clinics for treating parenteral drug abusers, and clinics for examining prostitutes.

On February 24-25, 1987, CDC convened a conference to discuss public health, medical, and public policy issues related to broader implementation of AIDS antibody testing. Approximately 700 people from public health, clinical medicine, professional organizations, AIDS support groups, and other affiliations attended. Following the conference, CDC has been working with representatives from the Association of State and Territorial Health Officers, the Council of State and Territorial Epidemiologists, the National Association of County Health Officials, and the United States Conference of Local Health Officers to review the results of the conference and to explore the need for additional recommendations concerning HIV antibody testing.

The AIDS Prevention cooperative agreements also include a health education/risk reduction component. In all of the 58 participating States and metropolitan areas, information and education activities have been initiated and work has begun to define, in detail, their AIDS problems. To date, 21 projects have targeted informational services to black communities and 15 have activities aimed at their Hispanic populations. Many projects have provided high-risk individuals with AIDS education and prevention messages through previously existing community organizations and support groups.

Veterans Administration facilities have long participated in controlling communicable diseases in this country through the treatment and prompt reporting of cases to public health authorities. With this history the VA can be an important element in a communitywide program of AIDS prevention. VA staff need to be fully informed about AIDS to educate patients and their families. Also, VA professional staff need to determine when they are serving persons with risk factors for AIDS and refer such patients for voluntary counseling and testing. Materials need to be available for use by VA personnel in educating those they serve. Through reports, we know that VA facilities have been diagnosing AIDS patients and through anecdotes, we know that many VA personnel have become active in the AIDS prevention efforts of their respective communities. The VA is to be applauded for their AIDS control work. We urge that their activities be closely coordinated with the AIDS Surveillance and Prevention programs which CDC is supporting through State and local departments of public health.

HEALTH WORKERS

Health workers must be prepared to address the health needs of infected persons and to counsel them, or refer them for counseling, to help reduce their risk of transmitting the virus to others. Our Nation's health workers represent a major channel for providing accurate AIDS information to patients, their sex partners, friends and family members, allied health care workers, and the public. Additionally, some health care workers, by virtue of their occupation, need to be informed that there is some very small risk of infection and how to avoid it.

CDC has been engaged in a wide variety of AIDS prevention activities including publishing guidelines in the MMWR, distributing slide series in response to nearly 4,000 requests, providing camera-ready copies of the Surgeon General's Report on AIDS to all AIDS program coordinators, and conducting training courses for laboratory workers in the latest techniques. In 1987, CDC will provide additional specialized training to program coordinators, AIDS health educators, AIDS antibody test counselors, and other health providers. We will also be developing training modules and educational materials to train both practicing dental professionals and dental students about infection control procedures, with an emphasis on AIDS.

PHS has worked with many professional and medical associations in efforts to reach their members with current information about AIDS. CDC is collaborating with the Health Services and Resources Administration in that agency's efforts to establish a network of AIDS Regional Education and Training Centers. These centers will provide health care workers with current information on the clinical management of AIDS patients. We have also published PHS guidelines on infection control and will continue to emphasize the importance of their adoption at every opportunity.

Whether to initiate HIV antibody testing in various health care settings and under what circumstances are being deliberated at every level. Testing within VA facilities is part of that debate. Current PHS recommendations advocate the counseling and testing of persons with risk factors for AIDS. This reflects a concern that broadly-based testing which overlooks this criterion is not likely to be cost-effective. The same concern and criterion apply to health care workers.

Regardless of any decision on the application of testing, we should recognize the need to provide counseling for those tested, especially for those who are seropositive. The view of PHS and the experience of CDC AIDS Prevention programs is that the opportunity for risk-reduction education through counseling is the vital preventive component of the counseling and testing effort. Education is our tool to reduce HIV spread and test results merely help reinforce the counseling message provided. Testing without the opportunity to offer that education, therefore, may be of very limited value.

On February 24-25, 1987, CDC convened a conference to discuss public health, medical and public policy issues regarding AIDS. Approximately 700 people from public health, clinical medicine, professional organizations, AIDS support groups, and other affiliations attended. There was consensus among the participants that the confidentiality of HIV antibody testing information is of great concern and that confidentiality must be strengthened if we are to reach those at high risk. The group also stressed that measures enacted to protect HIV testing information from unauthorized disclosures need to include penalties for violations, clarification of public health reporting responsibilities, and appropriate procedures to handle urgent organ donation and spousal or steady sex partner notification situations.

I have very briefly highlighted some of our knowledge about the nature of HIV infection, patient and geographic information on AIDS cases reported nationally and more specifically reported through the VA medical system, and an overview of educational and prevention programs. There is additional important work going on in AIDS in the PHS, many other Federal, State, and local government agencies, and in voluntary organizations. All have contributed to this Nation's effort to deal with this major modern-day scourge.

This concludes my testimony. I will be happy to answer any questions you may have.

Veterans
Administration

Memorandum

Date AUG 21 1987

From General Counsel (023)

Subj Legality of Routine Testing of All VA Patients for Antibodies to the AIDS Virus

To Chief Medical Director (10)

1. The AIDS epidemic has raised many difficult questions for both the medical and legal professions, and for the Veterans Administration. We find occasion to consider several of those questions in responding to your request for our views on the lawfulness of VA's routinely testing all patients who present themselves for treatment at VA health-care facilities for antibodies to the AIDS virus. In reviewing these questions, it is our understanding that VA itself has not to date developed a proposal or specific plan for such routine testing. As we understand it, however, the concept involves such testing being done as part of the physical examination and laboratory workup that is routinely performed on most patients being admitted to VA health-care facilities. For most patients entering a VA medical center, a blood specimen is routinely taken as part of a VA admission's "workup." It is our understanding that if routine testing were to be implemented that a slightly larger quantity of blood -- enough to fill an additional small test tube -- would be collected for that express purpose. The serum component of that specimen would be tested for antibodies to the HIV virus. The specimen would be reserved for follow-up confirmatory testing, if indicated.

Background

2. Questions regarding AIDS testing arise in midst of what has been described as a growing epidemic. The Centers for Disease Control of the Public Health Service (CDC) recently testified to having received reports of more than 36,000 cases of the disease known as acquired immunodeficiency syndrome (AIDS). A CDC spokesman estimated that by the end of 1991 the cumulative total of AIDS cases in the United States would reach 270,000 with nearly 180,000 deaths. It is our understanding that medical science has implicated the human immunodeficiency virus (HIV) as the direct cause of AIDS. It is widely recognized that risks of communicability of AIDS exist with respect to activities involving the transfer of blood and semen particularly, between individuals by means such as sexual contact, parenteral exposure to infected blood or blood components, or contaminated needles or transfusions; and perinatal transmission from mother to newborn. Recommendations for Preventing Transmission of Infection with Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus in the Workplace, 34 Centers for Disease Control: Morbidity

and Mortality Weekly Report (MMWR) 681 (November 15, 1985) (*Workplace Recommendations*). HIV-infected individuals include those who have serologic evidence of infection (test positive for the AIDS antibody) with HIV. *Workplace Recommendations, supra*.

3. What is commonly referred to as "AIDS testing" are procedures for detecting in blood samples antibodies to the virus which has been implicated in causing AIDS. Currently, initial screening for antibodies to the HIV virus involves the use of an enzyme linked immuno-sorbent assay (ELISA), a licensed commercially-available test used to screen blood and plasma. When the ELISA is used to screen populations in whom the prevalence of HIV infection is low, the proportion of positive results that are falsely positive will be high. "Provisional Public Health Service Inter-Agency Recommendations for Screening Donated Blood and Plasma for Antibody to the Virus Causing Acquired Immunodeficiency Syndrome," 34 CDC MMWR 1-5 (January 11, 1985). Therefore, CDC has recommended follow-up testing after a positive ELISA, especially the use of another test known as the Western blot screening technique. Data regarding the interval between HIV infection and the development of antibodies detectable on testing suggest that there may be a period of several weeks to three months before "seroconversion" occurs. "ABC of AIDS," *British Medical Journal*, Vol. 294, 1603 (June 20, 1987). CDC reports that a majority of AIDS cases in this country occur among homosexual and bisexual men and intravenous drug abusers but that the infection is also being spread heterosexually by sexually active individuals. (Apparently, the number of "heterosexual cases" remains small.) CDC data shows that 89 percent of AIDS cases are in individuals between the ages of 20 and 49. Essentially all AIDS cases, CDC reports, are related to contact with persons with, or at risk for, AIDS, or born in countries where heterosexual transmission plays a major role.

Legal Authority For Routine Testing

4. Implementation of a routine AIDS testing program first requires that VA have basic legal authority for conduct of a program. In that regard, Congress has directed that there shall be a Department of Medicine and Surgery in the Veterans Administration, the primary function of which shall be,

> to provide a complete medical and hospital service, as provided in this title and in regulations prescribed by the Administrator pursuant thereto, for the medical care and treatment of veterans.

3.

Chief Medical Director (10)

The Administrator possesses very broad authority to carry o
that statutory mandate. Section 210 of title 38, United Stat
Code, provides, in part, as follows:

> (b)(1) The Administrator, under the direction of the President, is responsible for the proper execution and administration of all laws administered by the Veterans' Administration and for the control, direction, and management of the Veterans' Administration.

Section 621 of title 38, United States Code, provides, in part:

> The Administrator shall prescribe--
>
> > (1) such rules and procedures governing the furnishing of hospital, nursing home, and domiciliary care as the Administrator may deem proper and necessary;

5. The above statutory provisions authorize the Administrator to take all necessary actions to facilitate the operation of VA health care facilities, and to provide care and treatment to veterans. The Administrator has by regulation delegated to the Chief Medical Director authority to act on all matters assigned to the Department of Medicine and Surgery by statute (38 U.S.C. Ch. 73) and by regulation, except such matters as require the personal attention of the Administrator. 38 C.F.R. § 2.6(a)(1). Those sections grant these officials discretion and have been cited, together with other provisions, as providing authority to take action necessary for the protection of patients, employees, and visitors. *Op. G.C. 3-71* (February 16, 1971) (authority to inspect packages brought into a VA facility). These provisions have also been cited, for example, as authority for VA medical center employees to participate in community-wide disaster drills, an activity which will allow VA to be better prepared in an emergency situation, and be better able to provide care and treatment to veterans. *Unpublished Memorandum to the Acting Chief Medical Director*, (1-5 Authority of the Administrator, September 9, 1978).

6. We do not presume in this paper to evaluate the necessity for HIV testing as to some or all VA patients. That determination would appear to be within your office's expertise. Assuming, for purposes of analysis, however, that you believe that such testing is necessary or medically indicated, sections 210(b) and 621(1) would provide general authority for its conduct.

Thus, absent provisions of law or the Constitution which might limit the exercise of your discretion, we believe there is a basis in law to institute such testing as you deem necessary. If, on the other hand, you conclude that such testing is not necessary either for hospital safety or patient care needs, then we do not believe there is a basis in law to so proceed. Under such circumstances, the expenditure of medical care monies to carry out such testing would be unlawful. 31 U.S.C. § 1301(a); Accord 60 Comp. Gen 653 (1981).

Search and Seizure

7. The Fourth Amendment to the Constitution protects "the right of the people to be secure in their persons . . . against unreasonable searches and seizures . . . ." Obviously, VA employees are bound by the Fourth Amendment, and VA beneficiaries are entitled to its protection. The question, then, is whether the Fourth Amendment is brought into play by AIDS testing and, if so, whether its terms bar AIDS testing. The resolution of this question turns on whether AIDS testing by government physicians in a hospital setting, where such testing is not intended to detect whether the tested party has violated any law or governmental policy, is a "search" and, if so, whether such a search is "unreasonable." The courts have not yet addressed this question.

8. We note initially that traditional Fourth Amendment cases have arisen as challenges to the government's authority to investigate conduct which somehow runs afoul of governmentally-imposed laws, rules or policies. See, e.g., Schmerber v. California, 384 U.S. 757 (1966) (blood test to gain evidence of DWI violation); Katz v. U.S., 389 U.S. 347 (1967) (surreptitious recording of telephone conversation to gain evidence of bookmaking operation); Winston v. Lee, 470 U.S. 753 (1985) (surgery to remove bullet which would tie plaintiff to the scene of an attempted armed robbery); New Jersey v. T.L.O., 469 U.S. 325 (1985) (public high school principal's inspection of a student's purse initially to detect evidence of smoking violation, and subsequently for evidence of marijuana use and sales). Such cases can--and do--arise outside the context of criminal law enforcement. See, e.g., Camara v. Municipal Court, 387 U.S. 523 (1967) (municipal housing code inspection); Marshall v. Barlow's, 436 U.S. 307 (1978) (administrative inspections by OSHA inspectors); Wyman v. James, 400 U.S. 309 (1971) (caseworker home visits as a condition of AFDC benefits). But a common thread--at least until very recently--appears to have run through all of the search and seizure

cases; each had to do with the detection of behavior which violated *some* governmental rule or policy--even though prosecution might not follow such detection. It might, therefore, be suggested that the Fourth Amendment is not implicated by AIDS testing since, as we understand it, no suggestion is made that HIV infection violates any federal law, regulation, or policy. *See Schmerber*, *supra* at 771 (footnote 13) where the Supreme Court notes that blood tests are "routine" and "ritual" preconditions to entry into the military, "many colleges," and the state of matrimony and, significantly, makes no suggestion that blood testing for such purposes would even raise Fourth Amendment concerns. *And see Wyman*, *supra* at 317-318, where the Court noted that although,

> one's Fourth Amendment protection subsists apart from his being suspected of criminal behavior . . . [t]his natural and quite proper protective attitude . . . is not a factor in this case, for the seemingly obvious and simple reason that we are not concerned here with any search . . . in the Fourth Amendment meaning of that term. It is true that the governing statute and regulations appear to make mandatory the initial home visit and the subsequent periodic "contacts" (which may include home visits) for the inception and continuance of aid. It is also true that the caseworker's posture in the home visit is perhaps, in a sense, both rehabilitative and investigative. But this latter aspect, we think, is given too broad a character and far more emphasis than it deserves if it is equated with a search in the traditional criminal law context. We note, too, that the visitation in itself is not forced or compelled, and that the beneficiary's denial of permission is not a criminal act. If consent to the visitation is withheld, no visitation takes place. The aid then never begins or merely ceases, as the case may be. There is no entry of the home and there is no search.

See also *New Jersey v. T.L.O.*, *supra* at 335, where the Supreme Court stated that the Fourth Amendment applies to searches outside of the criminal context "because the individual's interest in privacy and personal security 'suffers whether the government's motivation is to investigate violations of criminal laws or breaches of other statutory or regulatory standards'"; AIDS testing is not an "investigation" and, more importantly, is not designed to detect the "violation" or "breach" of any law or "standard." *But see AFGE v. Department of State*, 662 F.Supp. 50 (D.D.C. 1987) where the district court apparently assumed--but does not specifically rule--that the Fourth Amendment is implicated by the inclusion of AIDS testing in foreign service officers' required medical exams prior to assignment abroad. *See also O'Connor v. Ortega*, 107 S. Ct. 1492 (1987) where the Supreme Court appears to have ruled that a government employer's search of an employee office implicates the Fourth Amendment, apparently even where the employer's objective is merely to advance "noninvestigatory, work related purposes," *Id.* at 1502, though in *O'Connor*, "the search in question . . . was plainly . . . investigatory in nature." *Id.* at 1508 (Blackmun dissenting).

9. Although *O'Connor* is itself arguably distinguishable as a case involving the rights of public employees, it may be viewed as eroding caselaw which, until then, had seemingly limited the scope of the Fourth Amendment's reach to investigatory intrusions into possible violations of laws, regulations, or rules. If *O'Connor* is indeed to be read that broadly there may remain a substantial question whether the Fourth Amendment is implicated by HIV testing. That is, do VA patients have a constitutionally protected expectation of privacy regarding the possible presence of AIDS antibodies in their blood?

> [A person's] Fourth Amendment rights are implicated [by a given inspection or test] only if the conduct of the [h]ospital officials at issue . . . infringed "an expectation of privacy that society is prepared to consider reasonable." *United States v. Jacobson*, 466 U.S. 109, 113 . . . (1984). We have no talisman that determines in all cases those privacy expectations that society is prepared to accept as reasonable.
>
> * * *
>
> [T]he reasonableness of an expectation of privacy . . . is understood to differ according to context . . . .

O'Connor, *supra* at 1497 (citations omitted). In addition to the required societal expectation of privacy, the cases also suggest that an actual expectation of privacy on the part of the individual in question must be present before the Fourth Amendment is implicated. *See*, e.g., *Dow Chemical Co. v. U.S.*, 106 S. Ct. 1819 (1986); *Katz v. U.S.*, *supra* at 361 (Harlan concurring) ("My understanding of the rule . . . is that there is a twofold requirement, first, that a person have exhibited an actual (subjective) expectation of privacy and, second, that the expectation be one that society is prepared to recognize as 'reasonable'.")

7.

Chief Medical Director (1

10. At this point, of course, it is not possible to state with certainty what an individual's, or society's, expectations (if any) of privacy are with respect to AIDS testing, particularly in view of the Supreme Court's own statement that no "talismatic" formula exists for making such an assessment. Shared experience tells us, however, that individuals fully expect to undergo an array of diagnostic tests (including blood tests) when they enter a hospital. Indeed, the very purpose for entry into a hospital is, in most cases, to gain the benefit of such tests. To state that individuals (and society) expect that the medical data which can be found in blood is to be kept private from the hospital itself--as opposed to individuals outside of the hospital--is, as a general matter, to conclude something which is contrary to the common understanding of all adults who have requested care and, accordingly, have "submitted" to routine diagnostic procedures such as visual observation, and the taking of the body's temperature and blood and urine cultures. It is not inconceivable, however, that a court would find HIV testing to be unique, taking into account such factors as stigma or concern with discrimination.

11. A conclusion by the courts that there is some reasonable expectation of privacy as regards such testing would not, however, mean that VA medical centers may not routinely test for HIV infection. As was stated in T.L.O.,

> [T]o hold that the Fourth Amendment applies to [a] search . . . is only to begin the inquiry . . . . [T]he underlying command of the Fourth Amendment is always that searches and seizures be reasonable[.] [W]hat is reasonable depends on the context within which a search takes place. The determination of the standard of reasonableness governing any specific class of searches requires "balancing the need to search against the invasion which the search entails." On one side of the balance are arrayed the individual's legitimate expectations of privacy and personal security; on the other, the government's need [to conduct the search].

T.L.O., supra at 337. Thus, even if it were to be assumed that individuals have some expectation of privacy which makes AIDS testing a "search" under the Fourth Amendment, the weight of that expectation will be balanced against, first, the intrusiveness of the search and, second, against the VA's rationale for conducting AIDS testing in order to determine ultimately whether such a search is constitutionally permissible.

12. We assume, in light of our discussion in paragraphs 4 through 6, above, that instituting routine HIV testing must generally be based on a medical judgment that such a policy is necessary or medically indicated to operate our medical centers safely in the face of whatever health risks you foresee. To date, of course, no such judgment has been made. We offer no view, accordingly, at this time in terms of assessing in whose favor--the patient's or the hospital's--the balancing referred to above might tip. We note, however, that in any such balancing process, when the individual's privacy interest is relatively weak, the burden on the government to show the strength of its interests is diminished, particularly when, as here, the government proposes to do nothing which adds further "intrusiveness" to the patient's health care.

The Constitutional Right of Privacy

13. The precise contours--and, in some quarters, even the existence--of an independent right of privacy in the U.S. Constitution continues to be the subject of much debate among judges and legal scholars. We assume that such a right exists, and that it may be implicated by the routine testing of VA patients for HIV. We conclude, however, that the constitutional right of privacy does not proscribe either the disclosure of AIDS diagnoses within the VA Medical Center, or, assuming a substantial Agency interest in conducting such testing is articulated, the routine testing of VA patients to detect the presence of HIV antibodies.

14. In Whalen v. Roe, 429 U.S. 589 (1977), the Supreme Court considered the question of whether a State statute could constitutionally compel physicians to report information to state public health authorities concerning the medically-authorized use of "Schedule II" drugs, including the identities of patients using such drugs by prescription. The Whalen Court appeared to accept the plaintiffs' contention that a "constitutionally protected 'zone of privacy'," Id. at 598, is implicated by such disclosures since individuals have an interest in avoiding the governmental disclosure of personal matters. See also U.S. v. Westinghouse, 638 F.2d 570 (3rd Cir. 1980); Doe v. DiGenova, 642 F. Supp. 624 (D.D.C. 1986). But see J.P. v. DeSanti, 653 F.2d 1080 (6th Cir. 1981). However, the Court declined to bar the disclosure in question, ruling as follows:

> [D]isclosures [to authorized employees of the New York Department of Health] . . . are [not] . . . meaningfully distinguishable from a host of other unpleasant

> invasions of privacy that are associated with many facets of health care. Unquestionably, some individuals' concern for their own privacy may lead them to avoid or to postpone needed medical attention. Nevertheless, *disclosures of private medical information to doctors, to hospital personnel*, to insurance companies, and to public health agencies *are often an essential part of modern medical practice even where the disclosure may reflect unfavorably on the character of the patient*.

Id. at 602 (emphasis added) (footnote omitted). Based on this expression of reality, and on its refusal to speculate that such information would be further disclosed without proper authority, *see*, also, *McKenna v. Peekskill Housing Authority*, 497 F. Supp. 1217 (S.D.N.Y. 1980), the Court upheld the constitutionality of the New York statute. Similarly, the "disclosure" of AIDS testing results within the VA Medical Center would not violate the patient's right to privacy--even if it were to be assumed that such test results might be viewed as an "unfavorable reflection" on the patient.

15. Inquiry pertaining to the right of privacy, however, does not end with the resolution of the question of whether VA-collected information may be "disclosed" within the VA. "[C]ases such as *Whalen* suggest that . . . government *collection* of data can threaten individual privacy . . . ." *Shane v. Buck*, 658 F. Supp. 908 (D. Utah 1985) (emphasis added). But, as was noted by *Shane*, "[t]he Supreme Court has not yet squarely confronted the issue of whether the right to privacy limits governmental powers relating to the collection of data concerning private individuals." *Id*. Two considerations call into question the view that courts would so extend this right. First, we note an apparent trend to limit privacy rulings strictly to situations involving "fundamental" rights or rights "implicit in the concept of ordered liberty" *See*, e.g., *Bowers v. Hardwick*, 106 S.Ct. 2841 (1986); *DeSanti*, *supra*. Second, we note a tendency by the courts to avoid the unnecessary articulation of privacy rights not already announced by the Supreme Court *See*, e.g., *Dronenbury v. Zech*, 741 F.2d 1388 (D.C. Cir. 1984); *NAATS v. Dole*, No. A87-073 (D. Alaska March 27, 1987). But even if the "collection" of AIDS data--i.e., testing--implicates the constitutional right of privacy, that merely means that a balancing analysis, like that discussed above in the context of Fourth Amendment analysis, must be undertaken to determine its constitutionality. *U.S. v. Westinghouse*, *supra*; *Shane v. Buck*, *supra*; *McKenna v. Peekskill Housing Authority*, *supra*. Such a balancing analysis necessarily

assumes that VA has articulated a sound basis, consistent with its authority, for such testing. As is noted above, we assume such a rationale would rest on determinations within the Department's expertise.

Application of the Doctrine of Informed Consent

16. Patients admitted to VA facilities are customarily required to give a blood sample for routine laboratory testing in connection with an admission physical examination. It is this blood sample which would be subject to the test for antibodies to the AIDS virus. The question is raised whether the doctrine of informed consent requires that the patient be informed that the AIDS antibodies test is being performed, and give consent for performance of that specific test.

17. The doctrine of informed consent was originally developed as part of the law pertaining to the intentional tort of battery. Under this doctrine, if a patient had not consented to the bodily touching entailed in a doctor's treatment, an action for battery would lie at common law. See Interbitzen v. Lane Hospital, 124 Cal. App. 462, 12 P.2d 744 (Dist. Ct. App. 1932). To avoid the charge of battery, a physician generally needed only to tell the patient he was performing the procedure and obtain the patient's consent. In the 1950's and 1960's, however, courts began to look beyond consent and consider whether the patient's consent was also "informed." Thus, in Salgo v. Stanford University Board of Trustees, 154 Cal. App. 2d 560, 317 P.2d 170 (Dist. Ct. App. 1957), the court stated:

> A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment.

Id. 317 P. 2d at 181.

18. In Mitchell v. Robinson, 334 S.W.2d 11 (Mo. 1960), a case in which a schizophrenic patient was subjected to electro-shock therapy and insulin subcoma therapy, the court focused on one principal element of informed consent, the duty of the physician to inform the patient of the risks attendant to a specific procedure. In Mitchell, the patient consented to the treatment but was not informed of the serious risks associated with treatment: fractured vertebrae, fractured legs, and various other injuries occurring during seizures induced by the procedures. The court stated:

> Thus, the serious hazards being admitted, the problem is whether in the circumstances of this

> record the doctors were under a duty to inform their patient of the hazards of the treatment, leaving to the patient the option of living with his illness or of taking the treatment and accepting its hazards. Mohr v. Williams, 95 Minn. 261, 268, 104 N.W. 12, 14, L.R.A., N.S., 439.

Id. at 15. The court stated further that:

> [T]he doctors owed their patient in possession of his faculties the duty to inform him generally of the possible serious collateral hazards; and in the detailed circumstances there was a submissible fact issue of whether the doctors were negligent in failing to inform him of the dangers of shock therapy.

Id. at 19.

In Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 404 (1972), the California Supreme Court identified two principal elements of informed consent: knowledge of alternative procedures or treatment, and the risks associated with them.

> To enable the patient to chart his course knowledgeably, reasonable familiarity with the therapeutic alternatives and their hazards becomes essential. Therefore, we hold, as an integral part of the physician's overall obligation to the patient there is a duty of reasonable disclosure of the available choices with respect to proposed therapy and of the dangers inherently and potentially involved in each.

Id. at 10.

19. A patient must be provided information to make an informed consent, but there is then a question of how much information must be provided. Must the patient be told of all possible risks and all conceivable treatment alternatives? The standard

established by the courts appears to be that the greater the risk, the more information that must be provided to the patient.

> As a general rule of thumb, if the risk of untoward result is statistically high, the patient should be informed regardless of the effect on his morale. If the risk is statistically low, but the consequence of the rare occurrence may be extremely severe, the patient should likewise be informed. On the other hand, if the statistical risk is low and its severity is not great, the physician may safely tailor his warnings so as not to excite the patient.

A. Holder, *Medical Malpractice Law* 229 (2d. ed. 1978). In *Cobbs v. Grant*, *supra*, the court wrote:

> First, the patient's interest in information does not extend to a lengthy polysyllabic discourse on all possible complications. A mini-course in medical science is not required; the patient is concerned with the risk of death or bodily harm, and the problems of recuperation. Second, there is no physician's duty to discuss the relatively minor risks inherent in common procedures, when it is common knowledge that such risks inherent in the procedure are of very low incidence.

Id. 502 P. 2d at 11. In *Truman v. Thomas*, 27 Cal. 3d 285, 611 P.2d 902, 165 Cal. Rptr. 308 (1980), the court, quoting *Cobbs*, wrote:

> This situation is not analogous to one which involves, for example, relatively minor risks inherent in [such] common procedures as the taking of blood samples.

Id. 611 P. 2d at 907. *See also* *Canterbury v. Spence*, 464 F. 2d at 788.

20. If the degree of risk from a particular procedure is very low, the doctrine of implied consent may often be involved. Thus, when a patient visits a physician, or, for that matter, seeks admission to a VA facility and sees a VA physician, the doctor generally performs a physical examination which commonly includes the drawing of blood, and the taking of a urine sample, both for routine laboratory testing. The patient does not ordinarily expressly consent to the examination, or to the

taking of bodily fluids for laboratory testing. The physician may state that he is going to perform a physical examination including laboratory testing, but he does not usually explain each part of the examination to the patient, or the risks, such as there are. Similarly, the physician does not ordinarily explain to the patient the relatively remote risks involved in drawing blood for testing. That point was made in a footnote in Cobbs:

> For example, the risks inherent in the simple process of taking a common blood sample are said to include hematoma, dermatitis, cellulitis, abscess, osteomyelitis, septicemia, endocarditis, thrombophlebitis, pulmonary embolism, and death, to mention a few. . . . One commentator states that California law does not require that the 'patient be told too much.'

Id. 502 P. 2d at 11 n. 2 (citations omitted).

When the patient submits to the routine physical examination including the drawing of blood and the submission of a urine sample, the patient has impliedly consented to the procedures by conduct.

21. Perhaps the seminal case on implied consent is O'Brien v. Cunard Steamship Co., 154 Mass. 272, 28 N.E. 266 (1891). In that case, a passenger's consent to a vaccination was implied from the act of joining a line of people receiving injections where notice of the need for vaccination for immigrants to the United States had been posted on the ship. Other more modern cases have found that a patient implicitly consents to a procedure when he or she submits to a common procedure, or to a procedure which is well known to the patient, perhaps having been performed on the patient before. See Charley v. Cameron, 215 Kan. 750, 528 P.2d 1205 (1974); Coppage v. Gamble, 324 So.2d 21 (La. Ct. App. 1975); Causey v. Dean, 280 So.2d 251 (La. Ct. App. 1973).

22. In summary, the case law shows that the essential purpose of informed consent is to disclose to the patient information about the risks of a particular medical procedure so that he or she may make an informed judgment about whether to permit the physician to carry out the procedure. To understand the risks, it is also necessary that the patient know the nature and purpose of the procedure, alternative procedures, the probability of the procedure being successful, and what may occur if the procedure is not undertaken. Furthermore, the

more invasive a procedure is, and the greater the risk of harm to the patient from the procedure, the greater is the physician's burden to disclose detailed information to the patient. Conversely, if there is minimal risk from the procedure, or if it is a common procedure that is well known to the patient, less disclosure of information is required by the physician. In the latter situation, the patient's consent to the procedure may be implied by his or her submission to the procedure without questioning it.

23. Informed consent in the VA is governed by a Federal statute, its implementing regulations, and by Agency policy manuals. That statutory provision, 38 U.S.C. § 4131, generally requires that the Administrator prescribe regulations establishing procedures to ensure that "to the maximum extent practicable" VA furnishes "all patient care" with "the full and informed consent" of the patient or, in appropriate cases, the patient's representative. Section 4131 thus vests discretion in the Administrator regarding how informed consent is to be administered in the VA. The implementing regulation, 38 C.F.R. § 17.34, outlines in greater detail the elements necessary for informed consent in the VA. The elements closely resemble the common law elements of informed consent discussed above. The regulation provides:

> To the maximum extent practicable, all patient care furnished under title 38, United States Code, shall be carried out only with the full and informed consent of the patient or subject or, in appropriate cases, a representative thereof. In seeking such consent, the practitioner who has primary responsibility for the patient or who will be performing the particular procedure or providing the treatment must inform the patient in language understandable to the patient (or where appropriate, the patient's representative) of the nature of a proposed procedure or treatment, as well as of the expected benefits; reasonably foreseeable associated risks complications or side effects; reasonable and available alternatives; and anticipated results if nothing is done. The patient should be given the opportunity to ask questions, to indicate comprehension of the information provided, and to grant permission freely and without any coercion for performance of a procedure or course of treatment, as well as the opportunity to withhold or revoke such permission at any time without prejudice.

15.

Chief Medical Director (10)

Finally, the VA's Department of Medicine and Surgery (DM&S) has issued instructions regarding the provision of informed consent in VA health care facilities. DM&S Manual M-2, Part I, Chapter 23, articulates the following policy:

> A physician, dentist or other practitioner with clinical privileges must inform a patient (or where appropriate, the patient's representative) of the name, nature and details of a proposed diagnostic/therapeutic procedure or course of treatment, as well as the indications therefor, expected benefits, associated risks, complications or side effects, reasonable and available alternatives, and anticipated results if nothing is done. This information must be provided in language understandable to the patient. The patient must have the opportunity to ask questions, to indicate a comprehension of the information provided, and to grant permission for performance freely, without fraud, duress, deceit or coercion, to withhold or to revoke such permission without jeopardizing the right to future medical care and treatment.

Id. at para. 23.02c(1)-(3).

24. The manual provisions by which the Chief Medical Director has implemented the regulation do appear to require more than the regulation. Specifically, patients must be informed of the name, nature, and details of diagnostic procedures. It should be noted, of course, that the manual provisions constitute a departmental policy, subject to change or clarification. The Chief Medical Director could easily revise that policy. Any policy clarification would, of course, have to be consistent with the statute and regulation's broad mandate to provide "full and informed consent."

25. When a veteran seeks admission to a VA facility for care and treatment, he or she ordinarily must undergo a procedure for the drawing of blood in connection with a routine physical examination. As noted, consent to the extraction of blood may be implied. An argument can be made then on the basis of the case law discussed above, that the law does not require that the patient be aware of, and consent to, each test that is subsequently performed on the blood once it is drawn. Thus, the argument would be that the testing of blood does not involve a medical procedure performed on the patient, and there is no physical risk to the patient from the testing.

Accordingly, this argument would lead one to conclude that the law would not require advising patients of the plan to conduct tests for antibodies to the AIDS virus.

26. Although there is little case law directly on point, a growing body of scholarship strongly suggests that given the serious ramifications of HIV antibody testing, such testing should not be undertaken without the informed consent of the patient. Hermann, "AIDS: Malpractice and Transmission Liability," 58 U. Colo. L. Rev. 63, 71 (1986-7); Weldon-Linne and Murphy, "AIDS-Virus Antibody Testing: Issues of Informed Conent and Patient Confidentiality," 75 Ill. B.J. 206 (1986); "HTLV-III: Should Testing Ever Be Routine?," 292 British Medical Journal 941 (April 5, 1986). It is noteworthy, in that connection, that the Public Health Service (PHS) on August 13, 1987, issued recommendations regarding AIDS testing of certain risk groups. According to published reports, PHS called for "routine counseling and testing" for specified risk groups, and stressed that individuals have the right to refuse the tests.

27. In conclusion, we do not believe that VA can prudently rely on a traditional view of informed consent which would define "injury" as referring simply to physical harm. As both legal and medical commentators note, positive test results (as well as the real risk of false positive readings) may result in extraordinary psychological and emotional injury, including suicidal behavior. Clearly such risks are material to a patient. See Cobbs, supra. In light of these considerations, we strongly recommend that you retain the policy set out in the manual cited in paragraph 23 above and require that AIDS testing proceed only with patients' full, informed consent.

Confidentiality of Records Statutes

28. The proposal to conduct routine HIV testing as a part of VA patients' preadmission laboratory "workup" has sparked controversy regarding the confidentiality of data on patient seropositivity. See, e.g., Hearing on Acquired Immune Deficiency Syndrome (AIDS) and the Veterans' Administration, U.S. House of Representatives, Committee on Veterans' Affairs, Subcommittee on Hospitals and Health Care, June 17, 1987. It should be noted, however, that VA records containing AIDS test results are covered by Federal laws which make the information contained therein generally, but not absolutely, confidential. While the VA may properly disclose otherwise confidential information, it also has the authority to protect against

17.

Chief Medical Director (10)

unauthorized third party access to such information. e primary statutory authorities for VA action in these matt s are found at:

a. 38 U.S.C. § 3301, which covers all VA claimant records, including VA medical records, and which specifically prohibits the disclosure, by the VA, ofbeneficiary names and addresses. However, that prohibition is not without exception. Under this statute a disclosure may be made where the individual who is the subject of the records involved, consents to the disclosure, or, under the authority of subsection (f), which would allow name and address disclosure on receipt of a written request for such disclosure from a civil or criminal health or safety law enforcement governmental agency, where such disclosure is for a purpose authorized by law to be carried out by the requesting agency. Subsection (j) of this section further requires that disclosures, made pursuant to subsection (f), must comply with the provisions of the Privacy Act of 1974, 5 U.S.C. § 552a.

b. 5 U.S.C. § 552a provides strict protection against the unauthorized disclosure of Privacy Act protected records or information. VA medical records are subject to the protections of this Act. Regarding AIDS test results that may be contained in such medical records, under the Privacy Act, a disclosure of such information from a patient's VA medical records would require the written consent of the patient, or would need to be in compliance with the following specific statutory exceptions to such consent requirement.

(1) Under exception (b)(3), disclosure may be made pursuant to a properly published routine use of the records involved.

(a) Within the Patient Medical Records system of records, the Agency has specific routine use authority to allow disclosures that are consistent with the requirements and purposes of 38 U.S.C. § 3301 (f), as well as where such disclosures would be in response to proper requests from other Federal agencies, and the information to be disclosed is necessary to the accomplishment of the official purposes of such agencies.

(b) Under the existing disclosure authority it is also arguable that disclosure of AIDS test results may be made to a patient's next of kin where such disclosure is consistent with good medical-ethical practice.

(2) Disclosure may be made pursuant to exception (b)(8) where there is a showing of a compelling circumstance affecting the health or safety of an individual.

(3) The Agency also has the authority to release AIDS test information to Agency contractors, who need the information in the performance of their contractual obligations. Such contractors would be subject to the same disclosure restrictions as the Agency. The VA may also disclose to insurance companies where such disclosure would assist in the recovery of costs incurred by the Agency in its AIDS testing efforts.

29. In essence, while the VA has disclosure authority, it is the policy of DM&S not to disclose without the consent of the involved patient. However, that policy also recognizes that under certain exceptional circumstances the Agency could and might make disclosures from medical records. Finally, as regards records containing AIDS test results, the VA has the statutory authority necessary to protect claimant records from unauthorized access by third party individuals, and exercises policy judgments in accordance with that statutory authority. DM&S representatives are reviewing their existing confidentiality policy, in light of the extreme sensitivity involved in AIDS issues, to determine if additional legislation might be required. Ultimately, it must be acknowledged, however, that Federal law does not preclude disclosure within the hospital setting. The Agency does exercise reasonable care to restrict disclosure of AIDS information to health care workers who have a need to know that information. Nevertheless, it is impossible to guarantee that such information will in no case find its way into the community.

Rehabilitation Act of 1973

30. Confidentiality issues associated with routine testing of patients for the AIDS virus raise questions regarding application of the Rehabilitation Act of 1973. Section 504 of that Act, 29 U.S.C. § 794, prohibits discrimination against the handicapped in Federal benefits programs. The results of the test would become a part of every patient's medical record, and

that record would be available to all of the health care staff in the medical center who may have anything to do with treatment of the patient. If a patient were to receive disparate treatment, or were to believe that disparate treatment was provided on the basis of his or her having tested positive, there may be Rehabilitation Act implications.

31. Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794, provides:

> No otherwise qualified handicapped individual in the United States, as defined in section 7(7) [29 U.S.C. § 706(7)], shall, solely by reason of his handicap, be excluded from the participation in, be denied benefits of, or be subjected to discrimination under any program or activity . . . conducted by any Executive agency . . . .

And section 706(7)(B) of title 29, provides in pertinent part:

> [T]he term "handicapped individual" means, for purposes of titles IV and V of this Act [29 U.S.C. §§ 780 *et seq.*, 790 *et seq.*], any person who (i) has a physical or mental impairment which substantially limits one or more of such person's major life activities, (ii) has a record of such impairment, or (iii) is regarded as having such impairment.

32. In light of the above provisions, it is clear that the VA's provision of health care services to veterans is an Executive agency benefits program within the scope of section 504 of the Rehabilitation Act. Assuming that a patient is qualified (eligible) to receive hospital, nursing home or domiciliary care from the VA under the provisions of 38 U.S.C. Chapter 17, the additional elements necessary to invoke the Act are a finding that the patient is handicapped, and a finding that the patient received disparate treatment solely on account of his or her having that handicap. Two recent cases have addressed the question whether one who has tested positive on an HIV antibody test is handicapped for purposes of the Act.

33. In *School Board of Nassau County, Florida v. Arline*, 107 S.Ct. 1123 (1987), decided on March 3, 1987, the Supreme Court held that a person suffering from the contagious disease of tuberculosis can be a handicapped person within the meaning of section 504 of the Act. In reaching its decision, the Court rejected the contention that discrimination based on contagiousness, rather than physical impairment, is not unlawful and cited the example of a person, covered under the Act, who

has a visible physical impairment which does not substantially limit that person's functioning:

> Such an impairment might not diminish a person's physical or mental capabilities, but could nevertheless substantially limit that person's ability to work as a result of the negative reactions of others to the impairment.

Id. at 1128-9.

34. In the *Arline* case, the court discussed, but did not decide, whether an individual with the AIDS virus is handicapped within the meaning of the Rehabilitation Act, regardless of whether the individual has any symptoms of AIDS. In a footnote, the court stated:

> The United States argues that it is possible for a person to be simply a carrier of a disease, that is, to be capable of spreading a disease without having a "physical impairment" or suffering from any other symptoms associated with the disease. The United States contends that this is true in the case of some carriers of the Acquired Immune Deficiency Syndrome (AIDS) virus. . . . This case does not present, and we therefore do not reach, the questions whether a carrier of a contagious disease such as AIDS could be considered to have a physical impairment, or whether such a person could be considered, solely on the basis of contagiousness, a handicapped person as defined by the Act.

Id. at 21 (footnote 7).

35. *Local 1812, AFGE v. Dept. of State*, *supra*, reflected the view that being a carrier of the AIDS virus is a handicap for purposes of the Rehabilitation Act. The court found no violation of the Act by the defendant, but made clear its view that infection with the AIDS virus is a handicap under the Act.

> Second, plaintiff asserts that the testing program violates Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 791-796i (1982), which prohibits discrimination against handicapped persons, *see* 29 U.S.C. § 794. . . . Persons who carry HIV *may* be deemed handicapped in one or both of two ways. It is enough if they are perceived to be handicapped. *See* 29 U.S.C. § 706(7)(B)(iii). In the present period of speculation and concern over the incurable and fatal

> nature of AIDS there is no doubt that a known carrier of the virus which causes it is perceived to be handicapped. . . . The Department of State . . . concedes applicability of the Rehabilitation Act on the ground that the great majority of HIV carriers are physically impaired and handicapped only for that reason, under 29 U.S.C. § 706(7)(B)(i), due to measurable deficiencies in their immune systems even where disease symptoms have not yet developed.

36. Like confidentiality of records statutes, therefore, the Rehabilitation Act represents another protection for those patients found to be seropositive in VA HIV testing.

Conclusion

37. In conclusion, resolution of the issues surrounding the lawfulness of instituting widespread HIV testing of all VA patients turns, in our view, on a medical judgment from the Department regarding the need for such testing. Assuming that such a determination is made and that those findings are consistent with VA's authority and mission, we believe that in view of the broad authority granted the Administrator, such testing would be lawful, and would not in our judgment be deemed to violate patients' rights under the Constitution. If, however, you conclude that testing all VA patients cannot be justified as being medically necessary or medically indicated we believe VA would be without statutory or appropriations authority to carry out such an effort. Finally, we strongly recommend that, because of the implications of HIV testing and the risks associated with positive (and false positive) test results, such testing not be undertaken without the patients' informed consent.

Donald L Ivers

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AMERICAN NURSES' ASSOCIATION
WASHINGTON, D.C.

TESTIMONY
OF THE
AMERICAN NURSES' ASSOCIATION
ON
VETERANS ADMINISTRATION AIDS POLICY

Presented By
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AMERICAN NURSES' ASSOCIATION

JUNE 24, 1987

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Mr. Chairman, I am Mary Foley, R.N., Chairman of the American Nurses' Association's Cabinet on Economic and General Welfare. I am employed as a Registered Nurse at St. Francis Memorial Hospital in San Francisco. I would like to thank you on behalf of the 188,000 members of the American Nurses' Association (ANA) and its 53 constituent state nurses' associations for this opportunity to address the Veterans Administration's AIDS policy.

ANA, through its state nurses' associations, has 24 collective bargaining units in VA hospitals and long-term care facilities. Registered nurses in the VA number 35,000 from junior to senior grades. Other nursing personnel swell the numbers to over 67,000. Nurses represent the largest group of health care workers in the VA system.

BACKGROUND

Over the past three years, ANA has issued a variety of policy statements on the various aspects of AIDS. The Cabinets on Economic and General Welfare and Human Rights have provided substantial leadership on the AIDS issue during this time. Association positions have generally incorporated and supported guidelines issued by the Centers for Disease Control (CDC). In essence, the ANA: 1) believes that the most effective tools for preventing the transmission of AIDS are education and preventive health techniques; 2) opposes discrimination against persons with AIDS or a positive HIV; 3) supports the availability of quality health care, the confidentiality of that care, and respect for the individual affected; and 4) supports increased funding for research and educational efforts.

As the professional nursing organization for registered nurses, ANA has incorporated the concepts of epidemiology and public health in its programs and activities. Community health nursing practice promotes the public's health. The programs, services, and institutions involved in public health emphasize promotion and maintenance of the population's health, and the prevention and limitation of disease. Public health activities change with advancing technology and social values, but the goals remain the same: to reduce the amount of disease, premature death, discomfort, and disability, all of which are present with the disease AIDS.

The history of public health in this country has included health education, health promotion, testing and quarantine to control the spread of infectious diseases. Public health experts believe that educational programs are the key to minimizing the spread of AIDS. The HIV virus is transmitted through intimate sexual, blood-to-blood, or body fluid contact. In the overwhelming majority of cases, the transmission of the disease can be effectively prevented by individuals voluntarily abstaining from well-documented high risk behaviors and activities. There are strong indications that carefully targeted educational programs and individual health counseling directed at changing high risk behaviors have been effective in combatting the transmission of AIDS. Therefore, educational efforts directed toward changing behavior continue to be crucial.

With the documentation of isolated cases of transmission through accidental exposure to infected blood products, the policy debate about mandatory or routine testing has intensified. Routine testing would occur when HIV screening is automatically incorporated into certain standard sets of laboratory work, and a patient could then request that the test not be done. Mandatory testing would occur when receipt of services is contingent upon submitting to testing, e.g., marriage licenses, and immigrants seeking temporary or permanent status. Mandatory testing could also result from federal legislation which would make receipt of federal funds for states, agencies, institutions, and certain other services contingent upon compliance with testing requirements by those bodies, e.g., prisons, hospitals, drug rehabilitation centers, and sexually transmitted disease and family planning clinics.

ANA has addressed the health care aspects of AIDS since 1983, when the Department of Health and Human Services announced AIDS was the "number one health priority." At that time, ANA stated that all people who have AIDS have a right to equitable and humanistic health care, including: (a) quality treatment, including nursing and social support services, (b) non-discriminatory use of current isolation procedures, (c) full explanations of research procedures, treatments and risks involved, (d) informed choice of treatment/research modalities, (e) confidentiality of the medical record, and (f) respect for privacy and significant relationships.

IMPACT ON HEALTH CARE WORKERS

During that time, ANA also announced its commitment to the occupational safety and health of nurses, particularly with respect to exposures to toxic substances and blood-borne diseases. ANA's House of Delegates stated that

> "Nurses for decades, have dedicated their careers to promoting the health and welfare of their own clients, to the extent that consideration of the nurses' health and welfare has been neglected; nurses are among health care workers in hospitals who routinely face exposure to toxic chemicals, gases, infectious disease ...; and nurses are among health care workers in the community who face exposure to physical harm from infectious disease;...
>
> (Resolved) That the American Nurses' Association assist nurses to identify and to report health hazards to appropriate government, health, and nursing agencies or associations; and ... that ANA continue to encourage research and investigative activities into occupational risks and health hazards encountered by nurses in the workplace."

As we all know, presently there is no cure for AIDS. It is a disease that is nursing intensive. Throughout the course of the disease, it is nurses who provide continuous nursing care during the hospitalization, in the home, and during the hospice phases of this fatal disease.

ANA stands in opposition to mandatory testing of health care workers because of the possible misuse of such confidential information on employee records and possible adverse insurance and employment actions. Voluntary testing has been effective to date, and testing policies must provide anonymity and pre and post-testing counseling. ANA is in disagreement with the Justice Department's legal opinion that an employer could dismiss an employee who has AIDS if the dismissal was prompted by fear of contagion.

ANA is utilizing CDC guidelines and the ANA Code of Ethics in promoting written protocols for workplace policies focusing on all infectious diseases. We have also urged that more funds be designated for AIDS research and stressed that nursing should be included in such biomedical and behavior research.

In its efforts to educate the nursing profession about AIDS, ANA has borne the cost of supplying nurses with over 6,000 copies of the Surgeon General's report on AIDS. We are also collaborating with the American Red Cross to educate health care professionals and the community about the disease prevention and health promotion actions which people can use to prevent the spread of AIDS. ANA distributed over 2,000 copies of the American Red Cross' educational booklet on AIDS.

ANA has recognized that education about the epidemiological aspects of the disease is not enough. We have promoted the education and training of health care workers in protective work practices to assure the occupational health of nurses while providing care to AIDS patients. The Association participated in the revision of CDC's Recommendations for Preventing Transmission of Infection with HTC-VIII Virus in the Workplace issued in 1985. Subsequently ANA has urged that nurses and all health care workers study and use the guidelines to assure the safety of health care workers and the welfare of the public.

ANA and its state nurses' associations have promoted the guidelines in professional seminars and educational meetings. We have urged the Occupational Safety and Health Administration (OSHA) to address the hazards of AIDS and other blood borne diseases such as Hepatitis. Since 1984, we have repeatedly urged the National Institute of Occupational Safety and Health (NIOSH) to release guidelines it developed after a task force study on occupational hazards of workers in health care. The ANA review of the draft guidelines demonstrates that occupational safety and health programs in hospitals are non-existent or embryonic at best. Among the hazards addressed in that NIOSH document are specific recommendations on employee exposures to AIDS.

The recent Mortality and Morbidity Weekly Reports (MMWR) by CDC have revealed that three health care workers, including a nurse, have seroconverted after exposures to blood and body fluids of patients, subsequently revealed to be sero-positive for AIDS. The reports also demonstrate that increased education and training of health care workers regarding the CDC guidelines for care of AIDS patients is needed. ANA has reaffirmed its support of the CDC guidelines for preventing transmission of AIDS in the workplace. However, we believe OSHA efforts in enforcement are needed to assure employer/employee compliance.

"These three cases provide dramatic evidence of the need for registered nurses and all health care workers to continue to be vigilant in their compliance with the guidelines established by CDC," according to Dr. Margretta Styles, ANA President. "Registered nurses have been in the forefront of providing quality care to victims of AIDS. It is critical that we maintain this commitment while adhering to necessary precautionary measures to protect ourselves and the public we serve."

The cases in question illustrate the need for nurses to demonstrate by example the need to observe professionally established infection control precautions. "These three cases do not signal the need for a change in procedures," Styles said. "They instead signal a need to reemphasize vigilance with established procedures. Nursing has a tradition of providing quality care to the victims of once fatal infectious diseases such as poliomyelitis, yellow fever and tuberculosis. This tradition of caring has always meant adhering to proper control procedures to curb the spread of disease. We urge the nursing profession to take a leadership role in continuing to provide safe and effective care to victims with AIDS."

These revelations of worker exposures to AIDS, and subsequent seroconversion, have resulted in an increased call for mandatory testing for AIDS of specific groups by some legislators, and most recently the President. ANA continues to oppose mandatory testing, as we believe aggressive disease prevention education for health care workers and the public about the known causes, transmission, treatment, care and prevention are the most effective tools to prevent the spread of the disease. We have repeatedly expressed our support of the Surgeon General's recommendations regarding preventive health techniques and public education.

In November 1986, ANA issued a statement on serologic testing of health care workers in response to legislative inquiries regarding employee health and safety. It stated:

> "Acquired Immune Deficiency Syndrome (AIDS) has been declared the number one health priority by the U.S. Public Health Service. As the public becomes more concerned about the disease, the pressure for routine screening for the Human Immunodeficiency Virus (HIV) antibody is likely to mount. Pressure is apt to focus on health care workers because of their unique role in caring for persons with AIDS, even though the Centers for Disease Control (CDC) does not recommend routine serologic screening for health care workers, regardless of routine

> participation in invasive procedures.
>
> The American Nurses' Association (ANA) opposes the routine serologic screening of health care workers for the HIV antibody. The HIV virus is transmitted through intimate sexual or blood contact. Therefore, the risk of HIV is transmitted only through intimate sexual or blood to blood contact. Routine serologic screening of health care workers for the HIV antibody will not improve patient care or provide additional protection against HIV transmission in the health care settings. Since the mere presence of HIV antibody in the absence of immunosuppression or symptomatology of Aids Related Complex (ARC) or AIDS does not affect or predict job performance problems or risk to patients, other employees or the affected employee, the employer has no need for such information. Additionally, since the mere presence of HIV antibody does not predict the eventual development of ARC or AIDS, it cannot be used accurately to predict insurance claims or increased costs for employee benefit plans.
>
> ANA does support employer testing if it is done in accordance with the medical surveillance routine recommended by the CDC to document the job exposure to HIV after an occupational accident. Serologic testing after on the job exposure to HIV may be crucial in establishing a workers compensation claim. Personnel policies should be developed for on the job exposure to HIV and address employer payment for initial serologic testing and follow-up tests, record-keeping and access to records, confidentiality, and medical and health counseling during medical surveillance. Health care workers must be encouraged to report occupational accidents and seek appropriate medical surveillance. They must also be assured that such actions will not be subject to retaliatory actions or that the information will not be used in legally impermissible ways."

In a related action, ANA filed an amicus brief with the U.S. Supreme Court, on September 15, 1986, in the case of School Board of Nassau County, Florida v. Gene H. Arline, involving a teacher who was fired after contracting tuberculosis. The Supreme Court held that people with contagious diseases are covered by the federal law which prohibits discrimination against handicapped persons in federally funded programs. ANA agrees with Justice Brennan who noted that, "Congress acknowledged the society's accumula[illegible] myths and fears about disability and disease are as handicapping as are the physical limitations that flow from actual impairment." ANA will continue to monitor the ethical, legal, and labor relations issues regarding AIDS, and will encourage employer/employee-developed policies for catastrophic illness that are compassionate and equitable to prevent discrimination and economic upheaval.

TESTING OF VA HOSPITAL PATIENTS

On April 1, the President declared AIDS Public Health Enemy Number 1, and called for mandatory testing of certain groups at the state and federal levels. Among those recommended to be tested for the HIV virus were patients who receive care from the VA. The President's statement also included an admonishment that those with AIDS not suffer discrimination. "This calls for compassion, not blame. And it calls for understanding, not ignorance... but care for them with dignity and kindness." However, he did not call for legislation or state action to protect against such discrimination.

Although ANA agrees with the President's admonishment that those with AIDS not suffer discrimination, we differ with his recommendations on testing of hospital patients. ANA agrees with Dr. Koop's statement in his report on AIDS: "Compulsory blood testing of individuals is not necessary. The procedure could be unmanageable and the cost prohibitive. It can be expected that many who test negatively might actually be positive due to recent exposure to the AIDS virus and give a false sense of security to the individual and his/her sexual partners concerning necessary protective behavior."

Public health officials almost universally oppose mandatory testing. The epidemiological benefits of testing do not support the redirection of resources from research and education to test a large body of people who are not high risk. The majority of hospital admissions fall out of the demographic parameters that predict disease prevalence. Mandatory testing raises several concerns: first, costs for hospital patients alone have been estimated above $100 million; second, the feasibility of providing the recommended counseling; third, the issues regarding positive prenatal test results affecting birthing decisions; and lastly, the paramount concern of confidentiality of test results. The latter issue raises particular concerns about discrimination in the areas of insurance, housing, and employment.

The VA has reported its caseload has ranged from 5.3-5.8% of the total number of AIDS cases reported to CDC. A review of the ten VA Medical Centers representing the highest number of cases indicates a correlation to the nation's highest prevalence areas. Although the Department of Defense report from its screening of military personnel may affect the numbers, it does not seem naive to expect that without large numbers of women or children as AIDS patients, testing of all VA patients will not prohibitively increase VA cases.

Testing of all VA patients would therefore not be cost effective. Many public health officials also say AIDS testing for hospital patients would be expensive and ineffective. Most health professionals think education is the best way to combat AIDS and protect health care workers. We have to break this cycle of fear. Nurses, doctors, and other health professionals must walk a fine line between unreasonable precautions and those needed to prevent AIDS exposure.

ANA agrees with the American Medical Association's (AMA) recent statement, "Public health authorities have advanced a plausible premise for their opposition to mandatory testing" for certain groups, ... "Until those premises are shown ... to be incorrect, a policy rejected by the vast majority of public health officials, including the Centers for Disease Control and the Surgeon General, cannot be recommended."

Additionally, the result of testing all VA patients is that a multitude of documentation must be maintained. The federal government has learned since the Freedom of Information Act (FOIA) was mandated that keeping certain information in organized systems or records makes an agency vulnerable as to that information. Although such testing information would not be available through

FOIA, keeping such records becomes a major undertaking.

We have already heard reports that a list of VA patients tested for HIV virus was found in an accessible copier after it was inadvertently left by someone, hopefully, performing official VA business. We shutter to think what the unofficial release of such information would have on a veteran's life in employment, housing or insurance.

ANA also believes that the potential for misapplication of such testing could affect the provision of health care to veterans, if the VA had to juggle its resources because of misinformed budget cutters. We agree with House VA Committee Chairman Sonny Montgomery (D-MS) that "the mission of the VA's Department of Medicine and Surgery (DM&S) is to provide health care to all eligible veterans." Therefore, we cannot endorse a VA policy which could diminish the capability of DM&S to fulfill its mission.

ANA supports the availability of voluntary, anonymous testing with informed consent and appropriate counseling. Individuals seeking services at drug rehabilitation, sexually transmitted disease, and family planning clinics should have access to confidential testing and counseling about health practices. Confidentiality of test results must be maintained to prevent discrimination, especially in such areas as insurance, employment, and housing. Regardless of whether individuals are found to be seronegative or positive, targeted health education programs and individual health counseling which addresses preventive health practices and the avoidance of high risk behaviors must be provided by qualified health professionals.

As Congressman J. Roy Rowland (D-GA) stated last week at the House Veterans Affairs Committee hearing, "It is paradoxical that the discovery and identification of this virus -- or perhaps several viruses and the way the immune system is attacked -- has required the most sophisticated medical technology that has been developed by man and yet we can control its spread by using the most basic medical principles and education.... Veterans are not resistant to the infection and the VA's infrastructure in research, medical education, and health care delivery is already being hard hit by the demands of AIDS."

The VA is presently experiencing shortages of health care personnel and the effective treatment of AIDS patients and provision of the requisite pre and post testing counseling of veterans tested for HIV virus will additionally tax its personnel resources. ANA urges the VA to use its resources for AIDS research and staff education and training. Health care professionals will not only need to be trained to counsel their patients, but will also need counseling themselves. Caregivers to AIDS patients will need counselors to combat stress, burn-out and fear. Adequate staff will be necessary to guarantee quality nursing care, but also to assure that nurses have the time and resources to comply with CDC guidelines.

Prevention of harm to personnel and patients in evidence of HIV infection, and control of transmission of HIV, are dependent on an aggressive disease surveillance and education program. It cannot be done without appropriate numbers of well informed professionals. Lastly, ANA would urge one consistent AIDS policy for caregivers in VA health care facilities.

We would also like to take this opportunity to call for a national commission on AIDS with effective development and implementation authority. ANA supported S. 63, introduced by Senator Ted Stevens (R-AK), and had urged him to include the VA among the Executive Branch members of the proposed legislative commission on AIDS.

In closing, I would reiterate that ANA, based on public health and humanitarian principles, concern about discrimination, established association policy and a lack of definitive research demonstrating the efficacy of testing programs, adopted the following at the 1987 House of Delegates:

> That the House of Delegates support the availability of voluntary, anonymous HIV testing with informed consent and appropriate counseling by qualified health care professionals and that those seeking services at drug rehabilitation, sexually transmitted disease, and family planning clinics have access to anonymous testing and counseling about health practices.
>
> That the House of Delegates oppose universal mandatory testing for antibodies to the HIV virus.
>
> That ANA continue to urge the federal government to devote substantial funds to support education, research, and treatment in the fight against AIDS.
>
> That ANA reaffirm its commitment to protecting the civil and human rights of persons affected with AIDS as well as those of the caregivers.
>
> That the House of Delegates acknowledge and reaffirm the commitment of the nursing profession to provide care to all people in need of nursing services regardless of the illness or the severity of that illness.
>
> That ANA urge all health care workers to become familiar with and the implement the Centers for Disease Control Recommendations for Preventing Transmission of HIV infection in the Workplace.

ANA pledges to continue its role in the community and the profession in promoting AIDS prevention and education. We hope that these hearings will result in a logical scientifically based VA health policy on AIDS.

TESTIMONY BEFORE THE UNITED STATES SENATE COMMITTEE ON VETERANS AFFAIRS

Wednesday, June 24, 1987

By
WOODROW A. MYERS, JR., M.D., M.B.A.
STATE HEALTH COMMISSIONER
STATE OF INDIANA

Representing the
Association of State & Territorial Health Officials

Senator Cranston, and members of the Committee, I am Woodrow A. Myers, Jr., a physician and the State Health Commissioner for the State of Indiana. I appear before you today in my capacity as President of the Association of State and Territorial Health Officials. Our Association is comprised of the chief health officials of the fifty United States, the District of Columbia and the United States Territories. As state health officials, we hold the leadership roles in public health in our respective states, both within the medical community and with our primary constituents - the citizens of our states. Our Association has worked closely with the Centers for Disease Control since the first days of the AIDS epidemic. There continues to be a free, open and frequent exchange of information and ideas between our Association and the CDC. We have provided testimony before Senate committees and those of the House of Representatives on numerous occasions and are pleased to do so again today.

Your Committee is considering the serious issue of the counseling and the testing for HIV antibody status of the patients served by the Veterans Administration Hospitals throughout the country. It has now been concluded by virtually everyone actively involved in this epidemic that testing and counseling are our major weapons against the spread of the disease. The questions with which we now wrestle with are questions of how to maximize the effectiveness of this strategy while we wait for our colleagues in biomedicine to provide a vaccine and an effective treatment. We have listed some of the questions that this Committee has considered, and will consider, and we have provided our Association's response:

Should Veterans Administration Hospitals test entering inpatients and outpatients for the presence of Human Immunodeficiency Virus antibody?

Our Association believes the answer is yes, but with important caveats. First of all, we believe that counseling and testing are inextricably interwoven. I am confident that officials in our Veterans Administration Hospitals are quite aware of the importance of counseling, for many patients are unaware of the importance of the correct interpretation of the results and the follow-up that is necessary, for both those with positive results and those with negative results and continued behavioral risk factors. Our Association also believes that counseling and testing are not necessary for every patient in the VA system. We know a great deal about the demographics of this disease and the behaviors that put individuals at risk. Cost effectiveness would be enhanced by physician selection of those outpatients and inpatients who fit the demographic profile of a seropositive patient, or who in history taking admit to behaviors that put them at risk. For instance, the World War II veteran admitted for one of multiple episodes of congestive heart failure, a typical VA admission, need not be counseled and tested unless specific behaviors put him or her at risk or blood transfusion occurred prior to the start of antibody testing protocols in our blood banks. Similarly, we do not believe that a patient who is tested and counseled at one point and time needs to be tested and counseled at every single contact point with the hospital in the future. The patient's risk status should be reassessed and if retesting or additional counseling are indicated, they should be provided as necessary.

If there is no treatment or vaccine, why should patients be tested and counseled?

It is vitally important for us to have accurate data on the rate of spread of the virus in our population. The VA Hospitals constitute a system where such information could be readily obtained. The CDC and state health officials would welcome data to better characterize the epidemiology of this disease.

Although there is no current treatment, it is felt by many involved in biomedical research with this virus, that soon we will prescribe antiviral medication for those individuals who are HIV seropositive in spite of the fact that they have not developed the clinical syndrome of "AIDS". It is therefore important that testing and counseling systems be in place such that when this expected change occurs we will be in the best position to provide medication and information to those for whom we have medical responsibility. In addition, I am convinced by my clinical contact with many patients, and by the data now emerging from studies in San Francisco and elsewhere, that behavior that places an individual at risk, or that places other individuals at risk, can change. In the counseling phase of the VA program, seropositive patients will be told of the activities that will put their loved ones at risk. We believe that most people will not choose after counseling to engage in behavior that has been equated by some to attempted murder.

Should patients in the VA system have an option for refusing HIV testing and counseling, even when clearly indicated?

In the United States thus far, we have held to the premise that an individual has the right to be informed of the care that they can and should receive, and that an individual has a right to refuse such care. The question is whether or not the HIV epidemic warrants a change in that philosophy. Our Association believes that a modification, rather than a wholesale change of that philosophy is indicated. Most physicians feel strongly that HIV testing and counseling needs to be effectively integrated into our normal, regular system of health care. When we design systems and approaches that isolate HIV related disease from other diseases, inefficiencies and distortions occur. For instance, I am unaware of any hospital that requires separate informed consent for VDRL (a blood test to determine syphilis), for detection of the organism that causes gonorrhea, or for detection of the presence of Hepatitis B surface antigen. With each of these diseases there can be associated societal or employment related stigma that could adversely affect the patient. Yet, there has been no cry for a separate documented statement that patients have been informed these tests will be done and that they have accepted the risks of having the test performed. In some hospitals, procedures akin to surgery, such as insertion of catheters into the heart, procedures with a degree of medical risk that far exceeds the medical risk involved in the collection of a tube of blood to determine HIV status, are performed without a separate consent form being obtained.

The primary reason for informed consent is for the patient to understand the risk associated with a given medical act. There is virtually no medical risk from collection of a sample of blood to determine HIV status; therefore, those of us who are proponents of informed consent for HIV are in essence telling our patients that some members of our society may act on the information surrounding their HIV status and our system of confidentiality may not be sufficient to protect them from such action. As members of the Committee may be aware, several states have passed statutes mandating that patients sign explicit forms prior to collection of blood for HIV antibody testing.

It is the consensus of our Association that given the perceived shortfalls in our systems of confidentiality, and given the real threat in some states of individuals losing employment, housing and insurance coverage that an explicit "right of refusal" for HIV testing and counseling should be a part of any testing program based either in the Veterans Administration Hospitals or in other hospitals or clinics.

As a physician, I must tell the members of this Committee that it bothers me a great deal that my colleagues in public health must take such a position in 1987 - a position that says in effect "we cannot trust the system" to treat patients with this disease with the humanity and the compassion that other patients receive and that all patients deserve.

Would a mandatory testing and counseling system impede those who need these services from receiving them?

There has been a great deal of debate of whether or not a mandatory testing system would serve to in essence "exclude" those who would benefit from testing and counseling services. Many argue that any "coercive" system would drive those whose behavior puts them at risk "underground". Others argue that if everyone were required to be tested and counseled within a given system, then no stigma would be placed on any one individual assuming the maintenance of confidentiality.

In my opinion, there is no convincing data to support either argument. There is a great deal of anecdotal experience from public health officials who work in settings where sexually transmitted diseases are frequently seen. Over the years, these dedicated public health workers have developed impressive track records at finding the contacts exposed to sexually transmitted diseases. Many of those officials cringe at the idea of a "mandatory system". On the other hand, we have never been faced with an epidemic of this magnitude where the outcome is certain, painful and deadly. Has our concern for the "collective good" overridden our concern for an individual's rights? Is mandatory testing a logical expression of our concern for the public's health. The answer is - that today, a true mandatory testing program, once instituted, would be difficult to control. There will be a great deal of pressure to make results available to a variety of users, results of individuals and results of subpopulations, users from within the public health community and users from entities from outside public health. The desire to institute mandatory testing comes at the same time that vigorous expanded voluntary efforts are occurring. Our Association believes that the voluntary efforts that each of our states is utilizing are thus far successful, and can be even more so in the future. We fully expect that certain populations where high risk behavior is prevalent, and where state laws govern such behavior, will lose the option to refuse testing. Several state legislatures have already moved in that direction, including my native Indiana.

We like to think of cost factors as secondary until someone has to pay the bill. State health officials are more aware than most of the cost of testing and counseling. Those costs are certain to increase, not only with the increasing number of people seeking testing and counseling, but with the projected need to text for additional strains of the Human Immunodeficiency Virus in the coming years. We hear of more accurate and less expensive tests for the presence of virus or antibody. We are told that the new generation of tests will be available soon. In the interim, we will continue to utilize the ELISA and the Western Blot.

In summary, the Association of State and Territorial Health Officials agrees with the need to test and counsel patients at the Veterans Administration Hospitals. Testing and counseling at all hospitals in the United States needs to be increased substantially. We believe that populations of patients can be selected that would allow our limited resources to be targeted to those most likely to benefit. We should take care to move diseases related to the Human Immunodeficiency Virus to the normal realm of all medical care, but in many states, discrimination against HIV positive patients is a major problem, and many state health officials feel that an explicit right to refuse the test is necessary and appropriate. We are pleased that you have asked the Association of State and Territorial Health Officials to contribute to these proceedings, and I would be happy to answer any questions that you may have.

ASTHO
ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS
1311A Dolley Madison Blvd., Suite 3A, McLean, VA 22101
Phone (703) 556-9222

Re: Use of the HIV antibody test for screening
Date: June 24, 1987

The continuing discussion of uses of the HIV antibody test is far from completed, and proposals such as that to make the test a routine part of admission to a facility operated by the Veterans Administration add to the debate. All public health officials are seriously considering how to make the test a part of a comprehensive HIV infection control program: one of our serious concerns is the apparent interest on the part of some federal officials to see the test as an end in itself. For the test to be useful with any population group, there must be a plan for the management of seropositive individuals, there must be a reasonable expectation that there will be some positive persons in the group to be tested, there must be a socially acceptable control or identification point at which persons are entered into the group, and the cost of the program must bear a reasonable relationship to the expected benefit. There is room to question whether admission to a hospital facility adequately meets these tests.

MANAGEMENT OF SEROPOSITIVE INDIVIDUALS

The original use of the antibody test was the blood bank, where the management decision is whether or not to use the donated blood for transfusion. This "plan" did not include a very complete answer to management of the donating individual, but protection of the eventual patient outweighed this concern. One reason HIV testing has not been more vigorously promoted in many settings is that the management of both seropositive and seronegative individuals is identical: education, counselling, and support for changes in sexual or drug use habits which foster spread of the virus. Because this message is identical for both currently infected and currently uninfected persons, the actual test is not necessary, though its availability may be an attraction to the setting in which education may occur. There is a distinctly different message for women of child-bearing age who are considering pregnancy, if they are sero-positive, but such persons make up a very small percentage of the VA patient population and will not be discussed further here.

EXPECTATION OF POSITIVES

The lower the rate of infection in a population to be tested, the more likely it is that any positive test results will be false positives, even with the use of retesting and confirmatory procedures. There is little benefit (if any) in identifying false positives; arguments against the use of the test in the population at large have focused on this issue. In any population group other than the general public, the relevant questions is "how likely is it that members of this group have put themselves in the path of the virus?" If the group includes a substantial number of intravenous drug users, of gay men, of promiscuously sexually active individuals, then a testing program may be useful to identifying those persons. In the general population, it is not considered likely that the group of individuals being admitted to hospitals is any more likely to be infected than the general public, and may in fact be less infected because it includes a larger number of the very young, who are not yet sexually active or using drugs, and the very infirm who may have had to curtail any such activities. Specialized units of hospitals may meet the test, however. These would include programs treating drug abuse problems, or clinical services treating those exposed to other sexually transmitted diseases. To the extent that there are such units with the Veterans Administration facilities, they should make the test available as has been recommended by the CDC and other public health authorities.

SOCIALLY ACCEPTABLE CONTROL POINT

Any mandate for universal testing of a group must be controlled at some socially acceptable point. While it may be advisable to individuals changing sexual partners to consider HIV testing prior to intercourse with the new partner, there is no social control point at which such testing could be imposed. Hospital admission has been used as a control point for other screening tests in the past - hospital admission routines have included screening for tuberculosis and syphilis at various times. At the time when those screens were instituted, there was less concern in general for the personal consent to care process, and a greater reliance on the health care provider as all knowing about what was good for the patient. Today, we expect that our physicians and other care-givers will inform us of their intentions, and allow an opportunity for us to decide what will and will not be done. Hospital entry does provide an excellent opportunity for a physician to offer HIV testing. The act of offering the test opens the door for education, which is needed, whether or not the individual is tested, and whether or not the eventual test is positive. If the test is "buried" with a "routine" admission blood test, and done without any prior interaction with the individual, an excellent opportunity for education has been lost, but the provider can develop the false sense of having done something to "stop the AIDS epidemic". Further, while the undetected tubercular patient may put roommates or care givers at risk during a hospitalization, the undetected HIV positive individual is not a risk to fellow patients. There is a slight risk to caregivers which can be managed by the simple practice of treating all blood products as potentially infectious, which is fact becoming the rule for all providers.

COST

Given the finite resources of our social systems, any decision to mandate a procedure such as a screening test will absorb dollars which would otherwise be available for other activities. In the case of HIV infection, dollars spent on the laboratory test could otherwise be used for education and counselling programs. All sexually active persons, and all of those involved with the abuse of intravenous drugs, need to both be informed and make behavior changes which will reduce spread of the virus. There does not seem to be adequate justification, therefore, for diverting any large financial resources from the educational effort to use of the test. Even if unlimited dollars were available, and the question of detracting from education were not real, the test should be instituted only if it will yield useful information.

It is most appropriate that the Veterans Administration consider the use of the HIV antibody test in its health care facilities. Those individuals who receive their services from the federal system should have access to care which is up to the standard suggested in the community at large, or perhaps even to those which are at the forward edge of positive movements which will better promote health. All practitioners in the VA system should be receiving continuing education about HIV, AIDS, and the appropriate use of the antibody test as a part of diagnosis, patient management, and education to prevent further spread of the virus. Education for patients should be readily available, and in conjunction with counselling, testing should be offered. Facilities should work with the appropriate local or state health authority to be sure that required reporting of test results is completed, and that the VA programs are coordinated with specialized local services for education and support. This will be a much more effective contribution to the eventual control of HIV infection than the mandate of an HIV antibody test at the point of admission for everyone seeking care from the VA.

AIDS
Action
Council

TESTIMONY OF

Ann E. McFarren, R.N.

Executive Director, AIDS Action Council

presented to the

U.S. Senate Committee on Veteran's Affairs

June 24, 1987

729 Eighth Street, S.E.
Washington D.C., 20003

Mr. Chairman and distinguished members of the Committee, it is a priviledge to testify before you today. I am Ann McFarren, Executive Director of the AIDS Action Council. The Council represents 300 community based AIDS service providers throughout the United States and is mandated with the responsibility to ensure a comprehensive and effective federal response to the AIDS epidemic.

As you are aware, since the first cases of AIDS were reported to the Centers for Disease Control, exactly six years ago this month, a total of 36,158 cases of AIDS have been reported. It is anticpiated that by 1991 over 270,000 cases of AIDS will have been reported. It is important to point out to you and the other distinguished members of the Committee, that the Public Health Service has stated this figure may be an underestimation by 20%.

These numbers only begin to describe the impact of AIDS. AIDS is fatal -- it is killing people every day. Already, over 20,849 Americans have died from AIDS. These individuals are predominantly between the ages of 20 and 40 --- in the prime of life. By the end of 1991 it is expected that the total number of deaths from this disease will be about 179,000.

From the beginning, AIDS has affected men, women and children from all walks of life. AIDS does not discriminate. To date, AIDS has primarily affected and killed a disporportionate number of gay and bi-sexual men and IV drug abusers. People with AIDS develop a variety of complex medical problems such as frequent infections, rare cancers which cause horrible disfigurement and hemmorrhaging, severe pain, weakness, debilitation, uncontrolled diarrhea and loss of mental faculties. There is no cure for AIDS. Unfortunately, for many individuals diagnosed with AIDS, death is often a welcomed relief from the overwhelming physical and mental suffering associated with this disease.

Presently, we are at a turning point in this epidemic. We have come to recognize that AIDS is a risk to all Americans who engage in high risk behaviors; not just those who are in the historic "high risk" populations. When the epidemic first emerged, a coordinated federal response to the epidemic was not in place. In the absence of public and private assistance, a then small but growing number of Americans took the challenge of providing care and services to People with AIDS (PWAs) and their loved ones as well as to educate the public. These individuals, most of them volunteers, make up the AIDS service providing organizations in over 90 cities across the country. Today, these organizations number 300 and serve all segments of society.

Previous witnesses have outlined for you the impact of the AIDS epidemic on the VA medical system. What I would like to highlight for you is the extraordinay grassroot response of these organizations throughout America which have served as a cornerstone in the national response to this disease. My reason for this approach is simple: community based AIDS service providers have demonstrated foresight, tremendous leadership, and remarkable responses to the multitude of needs of PWAs. They clearly have set a standard for the type of services and support which are necessary to adequately respond to this epidemic. The information we have gained from these community based service providers regarding the education and services they have provided can and should be extrapolated to other organizations, such as the Veterans Administration, in shaping their continued response to this epidemic.

The comprehensive model programs developed by the community based AIDS service providers fund and administer the majority of both local, state and regional AIDS care, education and prevention programs in the United States. The service delivery component of these organizations is rooted in the philosophy that PWAs must continue to live productive lives. Service delivery programs effectively provide emotional support services including counseling and buddy support systems; implement holistic health care programs; provide financial support and housing for PWAs; make available medical services and referrals; and, provide legal services.

Because education is the only weapon that we presently have to control further spread of this disease, service providers have become expert in AIDS education and prevention. They provide effective programs to disseminate comprehensive information on the transmission and prevention of AIDS which is culturally appropriate and sensitive to the target audience; provide street outreach education programs; train educators, health care professionals and emergency personnel; communicate AIDS information to the press; staff HOTLINES; and, provide technical assistance on the design, management and evaluation of AIDS education and service programs for other organizations.

Every state in the nation and more than 70 countries throughout the world have been touched by AIDS. This is a global crisis from which no constituency, no government, no individual can stand apart. Certainly in the United States we have reached a crucial crossroad.

Presently, our only "vaccine" for the prevention of this disease is education. As an adjunct to any educational effort, voluntary counseling and testing programs must also be available as an essential public health measure. If every American at least learns about AIDS now, we have a chance to stop the epidemic. If not, the epidemic could overwhelm an increasingly burdened health care system and lead to social and legal restrictions incompatible with a free society. The choice is ours.

In the late 1986, the U.S. Surgeon General and the National Academy of Sciences (NAS) -- the nation's highest health officer and its most prestigious scientific body -- released seperate reports on AIDS that together called for perhaps the most wide-ranging and intensive educational efforts recommended to date. The NAS report, citing a "woefully inadequate effort" by the Federal government stated that "...if the spread of the virus that causes AIDS-related infections is not stopped, the epidemic could well become a catastrophe." The message is clear. America's most respected health experts are saying that AIDS is everyone's problem and therefore we must all be part of its resolution.

It is imperative that we disseminate information about AIDS to effectively control this disease. The VA medical system must initiate a sweeping educational campaign, reaching out to all who seek care in VA facilities. In addition, special attention must be given to a targeted education campaign for individuals currently participating in the VA drug rehabilitation programs.

I have brought with me today several excellent examples of AIDS education materials. I would like to submit them for the record. AIDS education materials need to be honest and factural with content that is age appropriate and culturally sensitive to the target audience. The goal of educational programs should be to modify high risk behaviors which include: unprotected sexual activity with persons infected with or at risk of infection with the AIDS virus and sharing equipment of intravenous drug abuse.

Now I would like to discuss counseling and testing programs in the context of educational efforts. In reports released by the U. S. Surgeon General and the National Academy of Sciences, referred to previously in my testimony, it was recommended that our public health policy on HIV counseling and testing programs be voluntary. These programs must be designed as an educational tool which includes culturally sensitive counseling before and after testing. Counseling must include information regarding transmission of the virus and safer sex practices as well as medical and support service referrals for persons found to be HIV positive.

Mandatory HIV screening programs are appropriate as a public health measure for blood or blood products, organ or sperm donations. Additional mandatory screening programs would be financially burdensome and ineffective. The HIV test currently in use is based on the formation of antibodies after an individual is exposed to the virus. It may take up to four months for the antibody to appear in the bloodstream and result in a positive test for HIV infection. Therefore, an individual may have the virus but test negative when screened. A negative antibody test creates a false sense of security and may cause an individual to neglect responsibly taking appropriate precautions when engaging in high risk behaviors.

Legislative protection with punitive sanctions for unauthorized disclosure of antibody test results must be enacted to ensure the success of any counseling and testing program. Without the guarantee of confidentiality and anti-discrimination protection, these programs will not be successful.

Anti-discrimination protection of persons infected with HIV is the cornerstone of strong, effective public health policies. Legislation prohibiting discrimination in employment, housing and access to medical care needs to be enacted to protect persons infected with HIV. Direct and indirect forms of discrimination against persons infected with HIV should be discouraged and prohibited by either state or federal legislation.

As a nurse, I am aware that many of my colleagues advocate routine testing for hospital admission. I appreciate these concerns and understand the need to protect individuals in the workplace. In that regard, I was pleased to receive recently a copy of the American Hospital Association's guidelines recommending that the standard practice in clinical settings be the use of blood and body fluid precautions on all admissions. I urge policy makers to support this recommendation which provides adequate protection to all health care workers.

Mr. Chairman and distinguished members of the Committee, I urge you to assume leadership on this issue and consider establishing comprehensive education programs including the availability of voluntary counseling and testing services within the VA medical system. These programs must be targeted to veterans who seek care at these facilities as well as their families.

This concludes my formal remarks. I will be pleased to answer any questions you may have. Thank you.

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TESTIMONY OF

PAUL W. SCHAFER, M.D.

EXECUTIVE DIRECTOR

NATIONAL ASSOCIATION OF VA PHYSICIANS (NAVAP)

at the

HEARING ON ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

before the

SENATE COMMITTEE ON VETERANS AFFAIRS

WEDNESDAY, JUNE 24, 1987

AIDS TESTIMONY

My name is Paul W. Schafer. I am a physician, a surgeon. I appear here today in a strictly unofficial capacity in respect to the Veterans' Administration but rather as the Executive Director of the National Association of VA Physicians (NAVAP). I speak on behalf of the Veterans Medical Program and those health care professionals who serve therein. I am a product of the surgical residency program of the University of Chicago where after a brief stint on that faculty I left to become Professor and Chairman of the Department of Surgery at the University of Kansas School of Medicine in Kansas City. There I was actively involved in our affiliation with five hospitals of the VA System; namely, in Leavenworth, Wichita, Excelsior Springs, Topeka, and Kansas City. I later served as Chief of Thoracic and Cardiovascular Surgery at the Walter Reed Medical Center and there trained a generation of the Army's surgeons who served with distinction in Korea and Vietnam. I now continue my service in the federal public sector as the full-time Chief of Thoracic Surgery at the Veterans Administration Medical Center here in Washington, D.C. My current academic identification is as Professor of Surgery, Georgetown University.

The National Association of VA Physicians (NAVAP) Board of Directors has recently reviewed its previously published position on Acquired Immune Deficiency Syndrome (AIDS) (see attached copy as it appeared in the December 1985 issue of NAVAP NEWS)

We are now more than ever appalled by the words and actions of those who would fan the flames of an epidemic of fear and hysteria about this emotion-charged issue. Though much needs to be learned about this disease there is no scientific basis for yellow gloves to be worn by police handling street demonstrators or by court baliffs at arraignment proceedings. It is to be hoped that the 1988 elections will not become a field-day for demagogues who would make the yellow glove a campaign symbol.

We call the on the Veterans' Service Organizations to join us in protest of President Reagan's insulting inclusion of the Nation's veteran patients in his recent remarks about HIV antibody testing of prison inmates and aliens seeking to enter our Country. The Agency must not promulgate policies and actions throughout the VA Health Care Delivery System implementing such practices for our patients and the health care workers who serve them.

AIDS is recognized as a disease for which there is no known cure at the present time. It is an infectious disease for which the profession has well established procedures for management of afflicted patients and the workers who care for them. We urge observance of the Centers for Disease Control guidelines concerning precautions that should be taken in dealing with blood or body fluids in which the AIDS virus might be transmitted, precautions that are already taken in dealing with other infectious diseases such as hepatitis B. Surgical teams practicing aseptic technique to prevent infection of patients are at one and the same time protected from AIDS patients upon whom they operate. Viruses, bacteria, fungi, and parasites opportunistically infect the lungs of immuno-suppressed patients. Such life-threatening infections can be difficult to diagnose. I regularly operate on such patients to obtain lung tissue for biopsies that permit accurate diagnosis often leading to life-saving specific treatments.

AIDS is a blood-borne, sexually transmitted disease that is not spread by casual contact. It is obviously spread by drug abusers who use contaminated paraphenalia and it may be transmitted to a fetus by an infected mother. Our supply of blood products and blood for transfusion is now essentially safe due to screening of donor blood; however, tragic prior infections did occur, some revealed by the "look back" program.

The disease appears still to be largely confined to groups who exhibit high-risk behavior such as drug addicts, homosexuals, bisexuals, and their sexual partners. All present evidence suggests that heterosexual spread of the disease in America outside of these high risk groups has been much slower than the explosive spread which occurred within the groups. This probably has to do with the difference in trauma associated with anal and vaginal intercourse. Frequent, unprotected vaginal intercourse with high-risk partners without resultant infection underlines the observation that AIDS is a hard disease to get.

NAVAP is strongly opposed to compulsory mass screening of VA patients and health care workers. HIV antibody testing should be performed only when professional clinical indications justify that the test should be made, and no such test should be made without informed consent.

Much evidence exists that lowering of high-risk behavior results from education and counselling in connection with tests rather than from the specific results of testing. NAVAP encourages the development of effective educational and counselling procedures as opposed to compulsory testing which will scare high-risk groups from seeking medical care. Available VA funds should be expended for education, counselling, and research, not mass testing. The cost of testing all VA inpatients would be at least $50 million per year. Mass screening of low-risk people would result in an extremely low yield. False negative tests will provide a false security among health care workers. There is a six week to six month sero-conversion time in addition to which there are rare non-antibody producers. False positive tests which account for at least 50% of low-risk group positives, are expensive to work up and cause needless anxiety. The release of data concerning a positive test often results in loss of employment, housing, and insurance and would place VA at significant liability.

In summary, the National Association of VA Physicians is opposed to compulsory mass HIV antibody testing of veteran patients or the health care workers who serve them. Such tests should be specifically and professionally indicated and should be performed only with specific informed consent for HIV antibody testing. Voluntary confidential testing should be encouraged. We believe the VA should expend its funds on high quality education, counselling, research and patient care and on confidential testing of those who wish it. The VA should develop an active and aggressive education campaign for VA employees from physicians to janitors, which should include decreasing risk of exposure, and an understanding of the social and psychological consequences of HIV positivity.

Finally, this is no time for hysterical fear. AIDS is a serious problem for American society and its only present hope for containment is education. Fortunately, it still remains a very difficult disease to catch.

Standard Form 507

CLINICAL RECORD Dr. Michael Simberkoff-008	Report on ________ or Continuation of S. F. VA Form 10-1086 (Strike out one line) (Specify type of examination or data)

(Sign and date)

INFORMATION ABOUT A STUDY ENTITLED "HTLV-3 ANTIBODY TESTING"

You have been invited to participate in a Research Study to evaluate the significance of detectable serum antibody to one of the proteins of the HTLV-3 (Human T-cell lymphotrophic virus). As you may know this virus has been isolated from and antibodies to its proteins have been identified in, the blood of certain patients. These include subjects with acquired immune deficiency syndrome (AIDS), patients with pre-AIDS or AIDS related complex (ARC) and asymptomatic individuals considered to be at risk for AIDS including homosexual men, intravenous drug abusers, hetrosexual contacts of the above, and recipients of blood product transfusions. You have been told that you are one of the above or that you are a health care worker who has been exposed to such patients or their body fluids.

We are testing a method for detecting antibodies to the HTLV-3 protein and doing a follow-up study to determine its significance. The test is done with a sample of your serum. Blood (about 20 cc or 1 ounce) will be obtained from you with standard precautions. The test is known to give some false positive and some false negative results. If your serum is positive it may be sent to another laboratory to confirm this result by another method. At present the technology to rule out a false negative is not available.

We are not certain of the significance of a confirmed positive result. Therefore, we would like you to be followed by your doctors or the Infectious Disease Clinic of this Medical Center. Follow-up for several years may be necessary.

You should be aware of the results of your test. We ask you to contact one of the members of the Infectious Disease Section to learn the result and discuss it further. The physicians to contact include: Michael S. Simberkoff, M.D., Wafaa El-Sadr. M.D., Danny Berman, M.D., Gigi Diamond, M.D., or David Ruben, M.D. They can be reached at (212) 686-7500 extensions 645, 409, 776.

You should also be aware of the fact that the results of this test will be recorded in your medical record. This record is confidential, but it may be read by authorized medical personnel and can be released to outside individuals with your permission.

____________________ Subject's Signature

________ Date

(Continue on reverse side)

Page 1 of 2

PATIENT'S IDENTIFICATION (For typed or written entries give: Name—last, first, middle; grade; date; hospital or medical facility)	REGISTER NO.	WARD NO.

REPORT ON ______ or CONTINUATION OF ______

STANDARD FORM 507
General Services Administration and
Interagency Committee on Medical Records
FPMR 101-11.80 6-8

INFORMATION ABOUT A STUDY ENTITLED "HTLV-3 ANTIBODY TESTING"

You are free to refuse to participate in this study or to terminate participation at any time. This will not effect your treatment in this hospital or its clinics or your employment by the hospital. If you participate, your identity and results will be confidential but the data may be used in scientific reports and publications.

We invite you to ask questions at this or any time.

If you agree to participate, we ask that you sign this information sheet which indicates that you have read and understood it and the accompanying VA Form 10-1086 which is your consent to participate.

Subject's Signature   Date

Witness' Signature   Date

Investigator's Signature   Date

PART I-AGREEMENT TO PARTICIPATE IN RESEARCH BY OR UNDER THE DIRECTION OF THE VETERANS ADMINISTRATION

DATE

1. I, ______________________________ , voluntarily consent to participate as a subject
(Type or print subject's name)

in the investigation entitled HTLV-III Antibody Test
(Title of study)

2. I have signed one or more information sheets with this title to show that I have read the description including the purpose and nature of the investigation, the procedures to be used, the risks, inconveniences, side effects and benefits to be expected, as well as other courses of action open to me and my right to withdraw from the investigation at any time. Each of these items has been explained to me by the investigator in the presence of a witness. The investigator has answered my questions concerning the investigation and I believe I understand what is intended.

3. I understand that no guarantees or assurances have been given me since the results and risks of an investigation are not always known beforehand. I have been told that this investigation has been carefully planned, that the plan has been reviewed by knowledgeable people, and that every reasonable precaution will be taken to protect my well-being.

4. In the event I sustain physical injury as a result of participation in this investigation, if I am eligible for medical care as a veteran, all necessary and appropriate care will be provided. If I am not eligible for medical care as a veteran, humanitarian emergency care will nevertheless be provided.

5. I realize I have not released this institution from liability for negligence. Compensation may or may not be payable, in the event of physical injury arising from such research, under applicable federal laws.

6. I understand that all information obtained about me during the course of this study will be made available only to doctors who are taking care of me and to qualified investigators and their assistants where their access to this information is appropriate and authorized. They will be bound by the same requirements to maintain my privacy and anonymity as apply to all medical personnel within the Veterans Administration.

7. I further understand that, where required by law, the appropriate federal officer or agency will have free access to information obtained in this study should it become necessary. Generally, I may expect the same respect for my privacy and anonymity from these agencies as is afforded by the Veterans Administration and its employees. The provisions of the Privacy Act apply to all agencies.

8. In the event that research in which I participate involves certain new drugs, information concerning my response to the drug(s) will be supplied to the sponsoring pharmaceutical house(s) that made the drug(s) available. This information will be given to them in such a way that I cannot be identified.

I ______________________________
NAME OF VOLUNTEER

HAVE READ THIS CONSENT FORM. ALL MY QUESTIONS HAVE BEEN ANSWERED, AND I FREELY AND VOLUNTARILY CHOOSE TO PARTICIPATE. I UNDERSTAND THAT MY RIGHTS AND PRIVACY WILL BE MAINTAINED. I AGREE TO PARTICIPATE AS A VOLUNTEER IN THIS PROGRAM.

9. Nevertheless, I wish to limit my participation in the investigation as follows:

VA FACILITY	SUBJECT'S SIGNATURE
WITNESS'S NAME AND ADDRESS (Print or type)	WITNESS'S SIGNATURE
INVESTIGATOR'S NAME (Print or type)	INVESTIGATOR'S SIGNATURE

☐ Signed information sheets attached. ☐ Signed information sheets available at:

SUBJECT'S IDENTIFICATION (I.D. plate or give name - last, first, middle)

SUBJECT'S I.D. NO.	WARD

AGREEMENT TO PARTICIPATE IN RESEARCH BY OR UNDER THE DIRECTION OF THE VETERANS ADMINISTRATION

VA FORM 10-1086
SEP 1979

SUPERSEDES VA FORM 10-1086 JUN 1975, WHICH WILL NOT BE USED.

PART II - AGREEMENT BY SUBJECT'S REPRESENTATIVE TO ALLOW SUBJECT TO PARTICIPATE IN RESEARCH BY OR UNDER THE DIRECTION OF VETERANS ADMINISTRATION

DATE

1. I, ______________________________ am authorized to give consent
(Type or print name of subject's representative)

for ______________________________ by virtue of ______________________________.
(Type or print subject's name) *(Relationship, legal appointment, etc.)*

I voluntarily consent for this person to participate as a subject in the investigation entitled ______________________________
(Title of study)

2. I have signed one or more information sheets with this title to show that I have read the description including the purpose and nature of the investigation, the procedures to be used, the risks, inconveniences, side effects, and benefits to be expected, as well as other courses of action open to me and my right to withdraw the subject from the investigation at any time. Each of these items has been explained to me by the investigator in the presence of a witness. The investigator has answered my questions concerning the investigation and I believe that I understand what is intended.

3. I understand that no guarantees or assurances have been given me since the results and risks of an investigation are not always known beforehand. I have been told this investigation has been carefully plannned, that the plan has been reviewed by knowledgeable people, and that every reasonable precaution will be taken to protect the well-being of the subject.

4. In the event the subject sustains physical injury as a result of participation in this investigation, if the subject is eligible for medical care as a veteran, all necessary and appropriate care will be provided. If the subject is not eligible for medical care as a veteran, humanitarian emergency care will nevertheless be provided.

5. I realize I have not released this institution from liability for negligence. Compensation may or may not be payable, in the event of physical injury arising from such research, under applicable federal laws.

6. I understand that all information obtained about the subject during the course of this study will be made available only to doctors who are taking care of the subject and to qualified investigators and their assistants where their access to this information is appropriate and authorized. They will be bound by the same requirements to maintain the subject's privacy and anonymity as apply to all medical personnel within the Veterans Administration.

7. I further understand that, where required by law, the appropriate federal officer or agency will have free access to information obtained in this study should it become necessary. Generally, I may expect the same respect for the subject's privacy and anonymity from these agencies as is afforded by the Veterans Administration and its employees. The provisions of the Privacy Act apply to all agencies.

8. In the event that research in which the subject participates involves certain new drugs, information concerning the subject's response to the drug(s) will be supplied to the sponsoring pharmaceutical house(s) that made the drug(s) available. This information will be given to them in such a way that the subject cannot be identified.

I ______________________________
NAME OF SUBJECT'S REPRESENTATIVE

HAVE READ THIS CONSENT FORM. ALL MY QUESTIONS HAVE BEEN ANSWERED, AND I FREELY AND VOLUNTARILY CHOOSE THAT THE SUBJECT PARTICIPATE. I UNDERSTAND THAT THE SUBJECT'S RIGHTS AND PRIVACY WILL BE MAINTAINED. I AGREE TO THE SUBJECT'S PARTICIPATION AS A VOLUNTEER IN THIS PROGRAM.

9. Nevertheless, my consent for the subject's participation in the investigation is limited as follows:

ADDRESS OF SUBJECT'S REPRESENTATIVE *(Print or type)*	SIGNATURE OF SUBJECT'S REPRESENTATIVE
WITNESS'S NAME AND ADDRESS *(Print or type)*	WITNESS'S SIGNATURE
SUBJECT'S NAME *(Print or type)*	SUBJECT IS NOW A PATIENT AT *(Name of VA Facility)*
INVESTIGATOR'S NAME *(Print or type)*	INVESTIGATOR'S SIGNATURE

☐ Signed information sheets attached. ☐ Signed information sheets available at:

SUBJECT'S IDENTIFICATION *(I.D. plate or print name - last, first, middle)*	SUBJECT'S I.D. NO.	AGE	WARD

AGREEMENT BY SUBJECT'S
REPRESENTATIVE TO PARTICIPATE
IN RESEARCH BY OR UNDER
THE DIRECTION OF THE
VETERANS ADMINISTRATION

VA MEDICAL CENTER WEST LOS ANGELES - CLINICAL LABORATORIES

INFORMATION ABOUT A.I.D.S. AND THE ANTIBODY BLOOD TEST (TO HTLV-III VIRUS)

WHAT IS A.I.D.S.?

Acquired Immunodeficiency Syndrome (AIDS) is a serious disease which reduces the body's ability to fight infection. Over the past several years increasing numbers of persons in certain high-risk groups have developed the disease, and by early 1985 about 9000 cases had been reported in the U.S. During 1984, a virus, Human T-Lymphotrophic Virus Type III - (HTLV-III), was discovered which is believed to be the cause of AIDS.

WHAT IS THE ANTIBODY TEST AND WHAT IS IT USED FOR?:

When a person is infected by a virus, the body normally begins to fight the infection by producing substances called antibodies. Antibodies can therefore be used to indicate whether or not a person has been infected by a virus. Research has shown that antibodies to the HTLV-III virus are usually found in the blood of persons who have AIDS or AIDS-related conditions, and in many people who are members of groups at increased risk for AIDS. However, a negative antibody test does not guarantee that a person is free of the virus, especially if he or she is a member of a group at increased risk for AIDS. Antibodies may not have developed if exposure to the virus was recent. That is why it is very important for members of groups at increased risk for AIDS to refrain from donating blood or plasma.

Present information suggests that only about 2% or less of blood donors who are not in the high risk groups will have an initial positive HTLV-III antibody test. When the test is repeated only about one-fourth of these will be positive a second time. Thus it is expected that less than 1% of donors (presumably the general population) will have the confirmed positive test.

Recently, tests for HTLV-III antibody were approved by the U.S. Food and Drug Administration to screen blood which is donated for use in transfusion and in the production of other blood products. All blood donations must be tested for HTLV-III antibodies.

WHAT DOES A POSITIVE ANTIBODY TEST MEAN?

The most important things to understand are that the antibody test is NOT a test for the actual AIDS virus, and that a positive test does NOT necessarily mean that the person will develop AIDS. A person may have been infected without any apparent illness. We are not able to predict which persons with the antibodies are more likely or less likely to develop AIDS.

As with many other blood tests, there will be some people who have test results which are called "false positives", that is, for some reason the test indicated that HTLV-III antibody is present when, in fact, it is not really HTLV-III antibody which is causing the test to register positive. When a positive test occurs, the laboratory will repeat the test. Many of the "false-positives"will be found to be negative on the repeat test. "False-positive" donors will not be reported to the Donor Deferral Register. However, the UCLA Donor Center will defer such donors until a new and more reliable test becomes available.

State Law requires that the Laboratory report the name and identifiying information of all persons with confirmed positive HTLV-III tests and/or Hepatitis test to a Statewide Donor Deferral Registry without stating the cause for the deferral.

(OVER)

PERSONS WHO MAY BE AT INCREASED RISK FOR A.I.D.S.

Anyone who has AIDS or one of its signs or symptoms.

Males who have had sex with more than one male since 1979, and/or males whose male sexual partmer has had sex with more than one male since 1979.

Past or present abusers of intravenous (I.V.) drugs.

Hemophiliacs.

Sexual partners (male or female) of persons in these groups.

VA MEDICAL CENTER WEST LOS ANGELES
CLINICAL LABORATORIES

CERTIFICATION OF RECEIPT OF INFORMATION AND CONSENT FOR TESTING BLOOD TO DETECT AIDS

(To be retained by the Clinical Laboratories)

I understand that my physician is requesting that my blood be tested for AIDS. I have received and read the Information about A.I.D.S. and the Antibody Blood Test HTLV III. I have been informed that this is a new test to detect antibody to the virus believed to be the cause of AIDS and that the reliability and accuracy of this test are not certain at this time. No other approved tests are currently available to detect the cause of AIDS. I understand that the test will sometimes indicate that a person has AIDS when the person does not, and in other cases, may fail to show that a person has AIDS.

I understand that if the test is confirmed positive, State Law requires that my name and identity be placed in a statewide Deferred Donor Register without listing the reason for the deferral.

I understand that the results of the test will be reported to my physician and may be entered into the Medical Record of the Institution, which I understand are confidential records. I understand that disclosure of results, except as above, will require my written authorization.

I acknowledge that I have had my questions answered regarding the nature of the test, possible benefits or risks, and consent to the performance of a blood test to detect AIDS.

Social Security # ____________________

Date ____________ Patient Signature ____________________

Print Name ____________________

Approved:

____
Infectious Disease M.D.

Ordering M.D. ____________________

____
Print Name
Beeper # ____________

WRITTEN QUESTIONS FROM CHAIRMAN CRANSTON TO DR. J. JARRETT CLINTON AND THE RESPONSES

1. I was very disappointed at the lack of emphasis in the DoD's testimony, and in the Department's April 20 policy memorandum on testing for the HIV antibody, on counseling -- both pre- and post- testing. I believe the Department should be aggressive in requiring and fostering appropriate counseling and working hard to ensure that fully adequate counseling is provided to each individual being tested.

I would appreciate your conducting an expedited review of the Department's counseling efforts in light of the strong position on counseling taken by the Centers for Disease Control and other public health officials. Please include in that review Assistant Secretary Mayer's assessment of the adequacy of current directives and practices and medical-staff training programs with respect to counseling. Please provide for the hearing record the results of the review and a description of what, if any, further steps the Department plans to take to expand counseling, and a timetable for completing any such steps.

Answer: Counseling and education are critical, integral and strongly emphasized components of our HIV policy and programs. The 20 April 1987 policy on identification, surveillance, and administration of personnel infected with HIV provides in paragraph B.5.a the specific requirements regarding the essential components of the counseling. These include a review of the significance of a positive antibody test (paragraph B.5.a1). The policy document continues by specifying the required counseling of identified case contacts who are military health care beneficiaries (paragraph B.5.a2). Furthermore the policy mandates in paragraph B.2.a "an appropriate and vigorous HIV/AIDS education program...to all beneficiaries of the military health care system...".

Our review of the Services' programs concludes that these requirements are being met and that no further major steps are necessary. In addition to our extensive use of U.S. Public Health Service and American Red Cross informational material, 1.6 million copies of a military specific brochure, "What You Should Know About HTLV-III and AIDS," were purchased and distributed. A revised version is planned. Films from outside sources as well as those created by the Services are used in the education program. Written materials regarding counseling rely heavily on materials created by other public agencies. Health care professionals utilize materials from a range of professional literature and informational meetings. We continue to assess any print or audiovisual materials prepared by the Services or by outside agencies for use in our HIV/AIDS education and information program. We will, of course, take into consideration any lessons of experience resultant from ongoing informal evaluation of these efforts throughout the Services. As a further step, we will conduct a formal review of our policy and its application in early 1988 as required by the April 20 memorandum from the Secretary of Defense.

2. Do you agree or disagree with public health experts who believe that counseling is important to guard against a sense of false security that a negative result may encourage?

Answer: We agree. Our education and information program incorporates this concept.

3. Paragraph F.1. of the DoD's April 20, 1987, memorandum stated that information obtained from a servicemember during or as a result of an epidemiologic assessment interview administered to each servicemember who tests positive for HIV infection may not be used against the member in a court martial or an adverse personnel action. However, paragraph F.3. seems to provide that the limitation in F.1. does not apply "to disciplinary or other action based on independently derived evidence".

A. Please describe the extent to which the "independently derived evidence" must be found to support the allegations before evidence derived from the epidemiologic assessment interview may be introduced and provide copies of any directive clarifying this matter.

B. Please provide copies of any documents explaining to the subjects of these interviews -- or to be used by persons who provide the subjects with explanations of — the uses to which the results of the interview may be used.

Answer: A. To be provided by General Counsel

B. Service practices vary in accordance with authorities provided to them.

C. Where are data from epidemiologic assessment interviews recorded?

Answer: Data are maintained with the primary physician, usually the infectious disease specialists. Copies are sent to the Service's research institution, for example, the Walter Reed Army Institute of Research, for analysis.

D. What organizational elements have custody of the data and under what circumstances are they permitted or required to disclose the data to command or law-enforcement authorities?

Answer: Medical elements have custody of the information. The information is not shared with command or law-enforcement authorities except as provided by the 20 April 1987 policy (see section F3).

E. Please provide copies of all directives governing the handling of information in these assessment interviews.

Answer: The 20 April 1987 policy document is the sole DoD goverring document. That policy is reviewed annually and modified as needed and approved. Service implementing documents are in the final draft stages and will be provided to the Committee when completed.

4. A. Paragraph B.1.a. of the April 20 memorandum specifies a priority order of initial testing and periodic retesting. The categories are very similar to those in the predecessor, October 1985, policy memorandum. Please briefly indicate the approximate percentage of each category that is tested each year. Please also provide detailed information broken down by service branch.

Answer: The Services were not directed to collect or maintain data on force testing by category. Force testing is nearly complete at this time.

B. The fourth priority category includes "medical personnel involved in the care of HIV infected patients, patients presenting at sexually transmitted disease clinics, patients admitted to alcohol and drug rehabilitation units, and patients at prenatal clinics".

(1) Are tests given to these individuals on the basis of voluntary, informed consent?

Answer: Testing is mandatory for active duty personnel. Testing is voluntary for all other beneficiaries.

(2) If so, please describe the consent process and provide detailed information, including consent forms, for the record.

Answer: The consent process follows the same procedures as for any pre-procedure counseling: an explanation of the rationale for the testing, the usefulness of the testing for the individual, and the limitations of the use of the information derived from the test.

(3) If not, do you believe that mandatory testing in this context may tend to discourage some individuals from seeking care at the medical facilities involved?

Answer: No, because mandatory testing is applicable only to active duty personnel, who are tested routinely in any case.

5. Subparagraph 2 of paragraph F of the April 20 policy memorandum provides;

> "Results obtained from laboratory tests for HIV performed under this memorandum may not be used as the basis for separation of the servicemember except for a separation based upon physical disability or as specifically authorized by this memorandum. Nothing in this subparagraph precludes use of laboratory test results in any other manner consistent with law or regulation."

Please (A) state which provisions of the directive specifically authorize the use of such laboratory results as the basis for separation of the service member based on a reason other than physical disability, and (B) describe the specific purposes for which the laboratory results may and may not be used under current law and regulations.

Answer: A. Paragraph A. of the April 20, 1987, policy memorandum authorizes the discharge of enlisted recruits, officer candidates, ROTC participants, and Service Academy cadets and midshipmen demonstrating serologic evidence of HIV infection. Occasionally, laboratory HIV test results are not received at the Military Entrance Processing Stations before recruits are enlisted in the Armed Forces. If a recruit's HIV positivity is first discovered upon arrival at basic training, the recruit is immediately discharged with an entry level separation. Similarly, HIV-positive officer applicants are ineligible for commissioning. Participants in officer commissioning programs whose HIV positivity is discovered during pre-appointment training are disenrolled from the program and thereafter discharged, unless entitled to remain on active duty to fulfill a pre-existing enlisted service obligation.

Under paragraph D. 2 of the policy memorandum, Service members with serologic evidence of HIV infection are subject to appropriate administrative and disciplinary action, including separation, for failure to comply with individual preventive medicine procedures. Additionally, under paragraph D.3, evidence of HIV positivity may be used, at the request of the Service member, for voluntary release from his or her service obligation at the discretion of the Secretary of the Military Department concerned.

B. The April 20, 1987, policy memorandum provides that the occurrence of HIV infection or serologic evidence of HIV infection may not in and of itself serve as a basis for disciplinary action. Also, Service members (other than recruits or officer candidates) on extended active duty (periods of more than 30 days), who show no signs of clinical illness or other indications of immunologic or neurologic impairment related to

HIV infection, shall not be separated solely on the basis of serologic evidence of infection.

The last sentence of paragraph F. 2 of the policy memorandum provides that laboratory test results may be used in any other manner consistent with law and regulation. For example, as discussed in paragraph B of the memorandum, positive serologic test results may be used as a basis for:

o Requiring a Service member to undergo periodic medical evaluations.

o Restricting a member's assignment to commands located in the United States, or placing other operational restriction on a member's assignment as determined by the Secretaries of the Military Departments.

o Conducting assessments of potential transmission (contact tracing) through appropriate military and state, local or foreign host national civilian health authorities.

o Conducting longitudinal epidemiological research.

o Counseling HIV-positive individuals and other military health care beneficiaries at risk of infection.

o Coordinating with military and civilian blood bank organizations for tracing possible exposure through donation or transfusion of infected blood.

o Providing case-contact information to cognizant military or civilian health authorities.

o Complying with communicable disease reporting requirements established by applicable state, local territorial, federal, or foreign host nation laws.

6. In the sentence at the bottom of page 13 of the DoD testimony, you state that the communicable disease reporting procedures of civil authorities are followed "to the extent consistent with DoD guidance". In what respects would DoD guidance most likely be inconsistent with the procedures of civil authorities?

Answer: Normally we comply with state and local health authorities reporting requirements. We would not follow a local reporting requirement, however, if DoD believed that the reporting requirement was not based on sound public health practices and science. For example, DoD would report only HIV positive individuals following Western Blot confirmation or its equivalent even if the local law required the reporting of all HIV ELISA positives, because to do so based on ELISA alone would be medically unsound.

7. Also, on page 13 of your testimony, with respect to follow-up efforts to reach the sexual contacts of personnel identified as infected with the HIV, you state that you generally provide local civilian health authorities with the names of contacts who are not eligible for military health care. In this regard, you indicate that the anonymity of the servicemember is maintained "unless reporting is required by the health jurisdiction." Why do you not adopt a federal policy of protecting anonymity in all cases?

Answer: Our primary objective is to cooperate with local officials in the containment of this disease in accordance with the laws established by them. To do otherwise would jeopardize the important collaboration on infectious disease control and other subjects of mutual interests. At the present time we believe that a federal policy to override state prerogatives unconditionally is neither warranted nor in the best interests of the Department of Defense or the public's health.

A. Why isn't anonymity a matter with respect to which DoD guidance prevails?

Answer: As previously noted, DoD has the authority to prevail over state law. We believe, however, that this power should not be abused. Only if a jurisdiction both required individual identity of a military beneficiary and demonstrated disregard for the confidential nature of this information would the DoD seek to prevail over the local jurisdiction's law.

B. Please obtain and provide for the record a DoD General Counsel's opinion on the issue of whether a DoD policy directive protecting the service member's anonymity could lawfully override a state or local requirement of disclosure.

Answer: To be provided under separate cover.

8. Please describe the AIDS research projects the Army is conducting.

Answer: The DoD AIDS research program for which the U.S. Army is the executive agent consists of four parts: Clinical studies done at Walter Reed Army Medical Center and the Walter Reed Army Institute of Research, focusing on the natural history and the pathogenesis of the disease in man; the following extramural research contracts:

Vaccine Development

Prediction and Testing of Antigenic Sites of the AIDS Virus, HTLV-III, Recognized by T-Lymphocytes, for the Development of Possible Synthetic Vaccines (NCI).

Test of Idiotype Manipulation with Monoclonal Anti-T4 Antibodies as a Potential Vaccine for AIDS (US FDA).

Characterization of African Human Retroviruses Related to HTLV-III/LAV (Harvard School of Public Health).

Use of Anti-Idiotypes and Synthetic Peptides for Control of Human T-Lymphotropic Virus Type III Infections (Southwest Foundation for Biomedical Research).

Antibody to the RNA-dependent DNA Polymerase of HIV; Characterization and Clinical Associations (NY Hospital-Cornell Medical Center).

Production of Acid-labile-alpha Interferon (ALAI) by AIDS Patients (Uniformed Services University of Health Sciences (USUHS)).

Mechanism of Cytotoxicity of the AIDS Virus (Washington University).

Immunopathologic Mechanisms of HIV Infection (Johns Hopkins University).

Pathobiology of HIV in the Human Monocyte/Macrophage (New England Deaconess Hosp.).

Analysis of the Human T-cell Response to HIV (Dana-Farber Cancer Institute).

Antigen Markers for Clinical Manifestation and Prevention of HTLV-III/LAV (Harvard School of Public Health).

Development and Evaluation of Adeno-HTLV-III Hybrid Virus and Non-Cytopathic HTLV-III Mutant for Vaccine Use (Biotech Research Lab).

Molecular Mechanisms of Cytopathogenicity of Primate Lymphotropic Retroviruses: Relevance to Treatment and Vaccine for AIDS (Biotech Research Lab).

Molecular Biology of STLV-III (Dana-Farber Cancer Institute).

Studies of Genetic Variation in the AIDS Virus: Relevance to Disease Pathogenesis, Anti-viral Therapy, and Vaccine Development (University of Alabama).

Comparison of Unidentified Viruses from AIDS Patients with Known Human and Animal Reference Viruses (Arbovirus Reference Center, Yale University).

Potential Benefits and Hazards of Humoral Immune Reactions Against HTLV-III/LAV (Karolinska Institute Medical School, Sweden).

Improved Diagnosis

Picornaviral Probes in Myocarditis Associated with the Acquired Immune Deficiency Syndrome (AFIP).

Plaque Transfer Assay for Detecting Neutralizing Antibodies to HTLV-III (US FDA).

Diagnosis of AIDS Related Intestinal Parasites (USUHS).

Development of a Sensitive DNA Assay for HTLV-III (Washington University).

Suicide Inhibitors of Reverse Transcriptase in the Therapy of AIDS and Other Retroviruses (George Washington University).

Inhibition of Gene Expression by Alkylphosphonate Oligonucleotide Analogs with RNase-like Activity (NCI).

Treatment of AIDS and AIDS-Related Complex (VA).

Antisense Oligodeoxynucleotide Inhibition of AIDS Virus Gene Expression (University of South Florida).

Sylvatic HTLV Related Viruses in South America (Yale U.).

Epidemiology of HTLV-III/LAV Infection in the Philippines (NAMRU-3).

The Impact of AIDS on the U.S. Army: Interviews with Seropositive New (Applicants for Military Service) (Research Triangle Institute).

Assessment of the Presence of Human T-Cell Lymphotropic Virus (HTLV-III) Antibody in Peru (NAMRID).

Nonvenereal Transmission of Human T-Cell Lymphotropic Viruses (HTLV) in Zambia (USUHS).

Assessment of AIDS in Western Asia (NAMRU-2).

Natural History

Biological Significance of the Immune Response to HTLV-III/LAV (Duke University).

A Longitudinal Study of HIV Infection in USAF Patients (USAF, Wilford Hall Air Force Medical Center).

Isolation and Characterization of HIV Viruses from Patients Under Study (Southwest Foundation for Biomedical Research).

Study of Cytomegalovirus as a Cofactor with HIV in the Etiology of Illness Seen in Patients (University of Texas Health Science Center).

Study of the Epstein-Barr Virus as a Cofactor in the Causation of Disease Seen in Patients (University of Texas Health Science Center).

Human Immune Response to HIV Virus Infections in AIDS (University of Massachusetts).

HIV: Intra-blood-brain Barrier IgG Synthesis and Hybridization in CSF Cells (VA);

inhouse laboratory research focusing on the quality control for HIV screening, development of new antigen detecting procedures, and virus growing procedures; and, extramural research support contracts which support both the inhouse research and the overall management of the AIDS research program.

9. Since HIV antibody testing of military applicants and, subsequently, active duty members and reservists began, how much has the Department spent on conducting the screening tests? How much does the Department anticipate spending for this purpose in FY 1988?

Answer: Funding for HIV Antibody Testing ($millions)

	FY 86	FY 87	FY 88
Army	12.4	17.8	17.8
Navy	4.9	5.2	5.3
Air Force	0.6	2.2	2.4
Total DoD	17.9	25.2	25.5

10. On page 4 of your testimony, you list the number of active duty individuals who are in the various stages of infection as determined under the Walter Reed HIV scoring system: 66 are classified as AIDS patients and 264 as having clinical manifestations equivalent to ARC.

A. How many are currently being treated in military hospitals?

Answer: DoD does not maintain a daily log of patients by diagnosis. Based on discussions with the Services, our major military medical centers have approximately 30 AIDS or ARC inpatients on a given day in 1987.

B. How many have been discharged?

Answer: The Military Departments report that as of June 29, 1987, 484 Service members have been retired or separated for physical disabilities related to HIV infection.

WRITTEN QUESTIONS FROM CHAIRMAN CRANSTON TO
DR. JAMES W. CURRAN AND THE RESPONSES

Question 1:

In your testimony you stated that 30 percent of HIV positive persons will develop a life-threatening disease within 7 years. I've read of estimates that the number can be as high as 70 percent over 10 years.

A. What reports was your testimony based on?

Answer:

The testimony on the natural history of HIV infection is based on a collaborative study, conducted by CDC and the San Francisco Department of Public Health, on a cohort of homosexual men. From an analysis of 155 cohort members whose date of HIV infection could be determined, it was estimated that 30% would develop AIDS after 7 years of infection.

B. Could you please clarify your understanding of those other estimates?

Answer:

No studies of persons with documented HIV infection for greater than 7 years have been reported. Therefore, any estimate of the rate of AIDS over 10 years of infection must be based on extrapolation rather than observation. The basis for an estimate of 70% of infected persons developing AIDS over a 10 year period is unknown.

Question 2:

A. With regard to the testing of individuals for HIV infection, is the main goal of testing to encourage those who either test positive or are at risk of infection to modify their behavior to prevent the further spread of the disease?

Answer:

Testing for antibody to HIV should be offered in conjunction with counseling. The main goal of counseling and testing has been to target prevention efforts to those at highest risk of HIV transmission and to provide information for behavior changes that reduce the risk of transmission.

B. In your personal, professional opinion, can that goal best be accomplished by education, information, and other types of outreach programs?

Answer:

A comprehensive information and education program including elements targeted at specific population groups is essential to reduce further spread of HIV infection. Offering routine testing and counseling programs to persons attending sexually transmitted disease, drug abuse, family planning, and prenatal clinics, as well as to others at risk of infection with the AIDS virus is the major outreach effort.

C. What needs to be done to educate high-risk groups about the need to seek tests?

Answer:

Widespread dissemination of educational messages followed by reinforcement through peer support, counseling or more specialized referral is the key. Those who perceive specific benefits of testing and counseling will seek out these services, which are available widely and are being expanded.

Question 3:

A. What are the most efficient, cost-effective means for obtaining accurate data on the rate of spread of HIV infection in the United States?

Answer:

The most efficient, cost-effective means are those which (1) make use of HIV infection data already available from other sources on an ongoing basis and (2) focus on the study of defined groups at highest risk of infection, e.g., persons attending sexually transmitted disease clinics, drug abuse clinics, etc. These types of activities will assist in targeting prevention and control effects.

B. What is CDC doing toward this end?

Answer:

CDC currently monitors the levels and trends of infection in military recruit applicants, National Red Cross blood donors, and sentinel hospital patients to evaluate spread of infection into the various demographic and geographic subgroups in the country. We are negotiating with the Job Corps to evaluate the data derived from their HIV screening of applicants. CDC assists State and local health departments, both technically and financially, in evaluating levels of HIV infection in accessible groups at potentially increased risk and for whom specific targeting of risk reduction efforts are appropriate: patients with sexually transmitted diseases, IV drug abusers at treatment centers, and childbearing women. These small, focused surveys are to help health departments identify the locally high priority target groups for intervention, monitor trends over time and evaluate the impact of risk reduction efforts.

Question 4:

In your testimony, you indicated that the CDC has learned through reports and anecdotes that VA health personnel are diagnosing AIDS patients and participating in AIDS prevention programs.

A. Would an interagency task force assist the coordination of the VA's efforts with those of the CDC?

Answer:

It is my personal opinion that the Veteran's Administration and the Department of Health and Human Services (DHHS), including CDC, are working well together already, and that such a task force is unnecessary. Also, both DHHS and the Veterans Administration are members of the Federal Coordinating Committee on AIDS Information, Education, and Risk Reduction.

B. Would it be helpful to the CDC if the VA has a centralized reporting system for statistics regarding ARC patients?

Answer:

The incidence and prevalence of AIDS-related complex (ARC) can best be determined through epidemiological studies or special surveys. Based on the past experiences of local health departments which, for surveillance purposes, required ARC reporting, data collected from a centralized VA reporting system would greatly understate the magnitude of ARC. In general, required reporting of HIV disease broader than case definition AIDS is not practiced. It is not realistic on a routine basis, since some of the milder manifestations of ARC may be poorly ascertained and reported (many ARC patients do not seek medical attention or do so in outpatient settings). A revised case definition for AIDS which includes the more serious ARC morbidity (e.g., chronic wasting syndrome and HIV-dementia complex) has been developed and will become effective nationally September 1, 1987. Completeness of reporting, estimated for the existing case definition at 90% or greater, is critical for accurately determining trends and for establishing meaningful comparisons with ARC and other HIV-infection data obtained from epidemiological studies and special surveys. Toward that end, we encourage the VA hospitals to continue working closely with State and local health departments in complying with all AIDS reporting requirements including the reporting of all patients meeting the expanded AIDS case definition.

Question 5:

On page 14 of your testimony, you state that at CDC's February conference, there was a consensus among the participants that the confidentiality of HIV antibody testing information must be strengthened if we are to have a successful counseling and testing program. In what way do you believe that medical confidentiality laws need to be strengthened?

Answer:

CDC can work with States and local jurisdictions in preparing model State confidentiality legislation to address this problem. In 1985 the National Conference of Commissioners on Uniform State Laws adopted model legislation entitled the "Uniform Health-Care Information Act." Although this model law (which has already been enacted in three States) does not specifically mention AIDS information, its carefully developed analysis of health-provider record confidentiality procedures can form a solid basis for further refinement. Additionally, the Federal Government should require that any programs supported by Federal resources will not tolerate inappropriate disclosures of confidential information. Such confidentiality provisions are already in place with respect to the sexually transmitted disease (STD) and AIDS prevention and control programs authorized under Section 318 of the Public Health Service Act.

Question 6:

A. What advice would you have for a health-care facility that is treating a recently divorced patient for ARC or AIDS and has received an inquiry from his ex-wife who asks whether the patient is or is not infected with HIV? Assume that the patient, contrary to his ex-wife's assertions, denies having engaged in sexual activity with his ex-wife since 1979 and withholds permission for release of any information to her.

Answer:

Difficult situations in family or other sexual relationships can arise whenever there are obstacles to communication among the persons involved. One function of a family practitioner is to help resolve these problems. Even in instances where satisfactory communication cannot be established, the risk to former sexual partners can be assessed without violating the confidentiality of other patients. In the example posed here, the attending physician can simply offer antibody testing to the inquiring spouse or can refer her to a counseling and testing site. Her infection status can be determined, even though, if she is infected, her source of infection could not be identified with certainty. Nonetheless, that is not the key issue; whether she is infected is the paramount concern.

B. In the same situation, assume that the patient does not deny having had sex with his ex-wife, but that the State involved does not have a contact notification system and the patient withholds consent to disclosure. What would you advise?

Answer:

The advice would not be different from that offered in question 6. A.

Question 7:

Do you believe that a specific informed consent form indicating that the patient has been counseled and fully informed as to the pros and cons of the test is advisable and necessary before an HIV test is done?

Answer:

It is my opinion that providing information necessary to obtain consent and the actual consent itself should be included in the process of pre-test counseling. Ideally, a person who requests testing or for whom testing is recommended should have a reasonable understanding of the medical and social aspects of HIV infection and the process of post-test counseling before giving his/her consent to be tested, which may be verbal or written.

AIDS
Action
Council

17 August, 1987

The Honorable Senator Alan Cranston
Hart Senate Office Building
Room 112
Washington, D.C. 20510-0501

Dear Senator Cranston:

In response to your recent letter requesting additional information on the American Hospital Association's Guidelines on HIV infection, I have enclosed a copy of the complete recommendations. I hope they are useful to you and the Committee.

Thank you for the opportunity to present the AIDS Action Council views at the Committee's recent hearing. We look forward to continuing to work with you and the Committee.

Sincerely,

Ann McFarren
Ann E. McFarren
Executive Director

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SUMMARY OF AIDS POLICIES AND RECOMMENDATIONS

Advisory Committee on Infections Within Hospitals of the American Hospital Association

The American Hospital Association has recently issued guidelines which recommend the following:

- For every hospital, precautions must be strictly followed whenever there is a possibility of exposure to blood or other body fluid.
- The use of gloves is required for all exposures to blood or other body fluid.
- Gowns, masks and eye coverings are recommended when the spraying of blood or other body fluids may occur as a result of procedures.
- Hands and other contaminated skin surfaces should be washed thoroughly and immediately if accidentally contaminated with blood or body fluids.

In making this recommendation, the Advisory Committee on Infections concurs with the CDC that universal use of blood and body fluid precautions represents the best means of protection of health care personnel against HIV transmission, rather than routine HIV testing of all hospital patients. Furthermore, reliance on negative HIV test results to determine when to apply specific precautions may lead to a false sense of security and the taking of unreasonable risk. Both the Advisory Committee on Infections and the CDC continue to emphasize, however, the value of HIV serologic testing for patient diagnosis and management on a selective case-by-case basis.

WRITTEN QUESTIONS FROM CHAIRMAN CRANSTON TO THE VETERANS' ADMINISTRATION AND THE RESPONSES

Question: 1.A. To approximately how many patients with ARC (i) has the VA provided care in total and in each of the past 3 fiscal years, and (ii) will the VA provide care in FY 1987?

Answer: The VA has no reporting system for ARC cases and there is no way at present to capture data on patients with that manifestation of human immunodeficiency virus (HIV) infection, since they are seen primarily as outpatients. New York VA Medical Center has a coordinated program to provide care to both AIDS and ARC patients and the staff there has noted an increase in patients with ARC seeking care:

	CY 1986		CY 1987 (6 mo.)	
	Inpatient	Outpatient	Inpatient	Outpatient
AIDS	132	99	87	95
ARC	21	36	28	64

San Francisco has likewise noted an increase in the number of ARC patients:

	FY 1986 (12 mo.)	FY 1987 (9 mo.)
AIDS	70	69
ARC	67	66

Question: 1.B. Does the VA have a system for reporting to Central Office all cases of ARC?

Answer: As stated above, there is no system for reporting ARC cases to VACO. Nor does CDC collect nationwide statistics on ARC.

Question: 1.C. If not, could you put one in place?

Answer: At this time, a reporting system for ARC would not appear to be necessary. Unlike the AIDS reporting system, it would not be building on an established, accepted national effort. Moreover, the International Code of Diseases has been revised to include codes for both AIDS and ARC and was accepted by the VA so that this information will be available through the Patient Treatment File for FY 87 and thereafter. However, the special Task Force studying reimbursement for AIDS and HIV-related disease is expected to recommend some method for accumulating data on HIV related illness including both AIDS and ARC in inpatient and outpatient settings.

Question: 2.A. How many HIV ELISA and Western Blot tests has the VA processed at its Lexington, Kentucky VA Medical Center laboratory in each of the past 3 fiscal years? How many of each will it process in FY's 1987 and 1988?

Answer: ELISA tests became commercially available in March 1985. The Special Reference Laboratory (SRL) started testing in April 1985. Western Blot kits became available in 1986. The SRL started testing in March 1986.

NUMBER OF TESTS

	ELISA	Western Blot
FY 85	450	--
FY 86	4,600	700
FY 87	8,000	1,800 (Projected based on 1st, 2nd and 3rd quarter totals.)
FY 88	10,000	4,800 (Projected based on maximum number possible without additional FTEE.)

Question: 2.B. How much did the VA spend in FY 1986 for AIDS testing and how much does the VA plan to spend in FY's 1987 and 1988?

Answer: In FY 86, testing for EIA and WB were performed at the Lexington Special Reference Laboratory (50%) and at individual VAMCs (50%). Although the Lexington data is firm, we do not know the volume of testing in other VAMCs. However, we believe that workload at all other VAMCs was approximately equal to Lexington's. Based on this assumption, we estimate costs as follows:

	Lexington	All Other VAMCs
FY 86	$ 82,754	$188,666
FY 87	$100,000	$215,000
FY 88	$125,000	$240,000

The FY 87 and FY 88 estimates are based on no dramatic increase in testing.

Question: 3.A. What percent of antibody tests currently being requested at VA medical centers are being sent to the Lexington facility?

Answer: Through FY 86, it is estimated that Lexington did approximately 50 percent of all tests done in the system. However, at present estimates are approximately 25-33% due to more VA facilities initiating screening of various patient groups. HIV tests for 85-90 different VA facilities are currently being done at Lexington.

Question: 3.B. How many individuals are employed at Lexington to process the HIV ELISA and the Western Blot tests?

Answer: Four FTEE are used for the current workload at Lexington Special Reference Lab.

Question: 3.C. How many new employees would you need at Lexington or elsewhere to process such tests in-house for 1.4 million VA inpatients per year?

Answer: If regional labs were used (the most economical choice) and incorporated into existing Pathology Services at large VA hospitals, 30-50 technicians would be needed, depending upon which commercial HIV system was used. In addition, each reference lab would need at least one mail clerk, one secretary (or clerk-typist), an additional technician for performing Western Blot tests and a supervisor. A total of approximately 60-70 employees would be necessary in this area.

Question: 3.D. What would be the cost of such testing if all done in-house?

Answer: It is estimated that the cost of doing the tests in-house for all in patients would be approximately $7,226,670. The exact figure would depend on the number of positive ELISA tests which would need to be confirmed by Western Blot.

Question: 3.E. What is the added cost per test when pre-and post-test counseling is provided?

Answer: It is difficult to calculate the cost of counseling per test since there is no uniformly defined "dose" of counseling. Appropriate counseling involves the availability of trained counselors with the amount of time dependent on the number of HIV positive people in the population being tested. A program to provide counseling to all inpatients which would have to rely heavily on existing resources, including doctors and nurses responsible for the primary care of the patients, is estimated to cost $8,016,000.

Question: 3.F. For what number of patients do you believe it would be feasible for the VA to do testing on an entirely in-house basis?

Answer: We believe that all patients could be tested "in-house" doing the ELISA at the individual VA medical centers. Western Blot or other confirmatory testing must be done in selected locations, regional labs, or the Serology Reference Lab to provide standardization and uniformity of results. No positive ELISA tests would be reported until the Western Blot was done and the result confirmed.

Question: 3.G. If required to test all inpatients for HIV infection, for how many ELISA and Western Blot tests per year would the VA have to contract out and at what average cost for each type of test?

Answer: If all VA medical centers did their own screening tests and sent confirmatory tests to the SRL, it should be possible to do all 1.4 million tests per year. If VA facilities individually sent out their tests to commercial labs, the cost would vary from approximately $15-60 for an ELISA to $25-100 for a Western Blot. If the VA system sets up a nation-wide contract with a commerical lab, the cost of 1.4 million would be approximately $20,703,000 for the laboratory contract and related collection, preparation and reporting costs. However, we believe that for reasons of quality assurance and confidentiality an in-house approach is preferable.

Question: 4. Do you believe that a specific informed consent form indicating that the patient has been counseled and fully informed as to the pros and cons of the test is advisable and necessary before an HIV test is done?

Answer: A specific informed consent form is not legally required to be completed before administering the test.

Question: 5. In your testimony, you estimate that the cost of medical care for an AIDS patient is $20,000 to $24,000 per year as compared to $40,000 a year ago.

5.A. How were these cost estimates determined?

Answer: The $40,000 was based on estimations from three VA facilities who had experienced high numbers of AIDS patients by 1985. From their data, it was determined that the average patient spent 66 days in the hospital in 2.8 admissions and had 15.7 outpatient visits. The calculations were made using the prevailing per diem and outpatient costs. Since 1985, Patient Treatment File Data has been evaluated and the average length of stay determined to be 23 days with a readmission rate of 1.8. Excessive drug costs, excluding AZT, were factored into each an average cost of $22,000 to $25,000.

Question: 5.B. How does the use of AZT affect this cost estimate?

Answer: AZT will increase the cost. It is unclear at present how many patients will require AZT, but those who do will cost at least $9,000 per year more as this is the basic cost of the drug. Additional costs related to monitoring and treatment of side effects would also have to be covered.

Question: 5.C. What consideration will be given to the cost of AZT in developing the adjustment to the RAM allocation for FY 1988?

Answer: AZT will be considered in developing the adjustment to the RAM allocation.

Question: 6. In your testimony, you indicated that you are evaluating the feasibility and desirability of identifying "AIDS Centers" in medical centers that are located in epicenters of the epidemic.

6.A. Would AIDS Centers have certain wards or floors dedicated to treating AIDS patients?

Answer: One AIDS Clinical Unit has been approved and a request for proposals for two others is being developed. The approved Unit will have both a dedicated AIDS ward and an outpatient clinic.

Question: 6.B. Would AIDS patients from other VA medical centers be transferred to the AIDS centers?

Answer: The AIDS Clinical Units are not being viewed as referral centers, hence the change in name from AIDS Centers to AIDS Clinical Units. They will help meet the special needs of medical centers providing care for large numbers of AIDS patients.

Question: 7.A. What steps is the VA taking to address through non-institutional alternatives and otherwise the long-term care and hospice needs of veteran AIDS patients?

Answer: The VA is committed to providing the full range of medical care to eligible veterans with AIDS. This is one of the areas the newly established VACO AIDS Working Group is looking into. There are programs already in operation such as the Hospital Based Home Care (HBHC) program at VAMC San Francisco that can serve as models for other medical centers in the system in providing non-institutional alternatives for care.

Question: 7.B. How many AIDS patients are in VA nursing homes?

Answer: We are aware of AIDS patients being treated in VA nursing homes. At this time, however, reporting systems that would identify AIDS patients in long-term care settings have not been developed. It is anticipated that in the future such information will be readily available.

Question: 7.C. To what extent, if any, have VA facilities experienced difficulty in placing VA patients in contract nursing homes or state-home nursing homes because the facilities were reluctant to care for AIDS patients?

Answer: We are aware of instances where nursing homes with VA contracts have been unwilling to care for AIDS patients. Under the terms of the contract, a nursing home has the right not to accept any patient. There have also been situations where AIDS patients have been successfully placed in the Community Nursing Home Program (CNH). One VA medical center has requested a special per diem rate to place AIDS patients in the CNH Program. The VA does not have the authority to establish specific admission criteria for the State Home Program. These criteria are set by the states. We cannot assess the relative difficulty of placing AIDS patients in State Homes.

Question: 8.A. Do you see any need to amend the laws relating to the confidentiality and privacy of HIV testing and test results in the VA? Would an amendment to section 4132 be desirable?

Answer: The results of an HIV test constitute patient medical record information, the confidentiality and privacy of which is protected under the VA's confidentiality statute (38 U.S.C. 3301) and under the Privacy Act of 1974 (5 U.S.C. 552a). Agency policy regarding the disclosure of individual identifiable AIDS testing data is to withhold its disclosure, except in certain exceptional circumstances, unless the individual to whom it pertains consents to such disclosure. At this time, the aforementioned statutes and policy application provide appropriate confidentiality and privacy protection to such information. If problems arise, as a result of the application of those statutes or policy in issues concerning AIDS test results, then our position in this matter will be reconsidered.

Question: 8.B. Is a review of existing laws, regulations, and practices currently being conducted to determine whether a need for such a change exists?

Answer: An informal review of existing laws and regulations, as they affect the confidentiality of AIDS test data, has been accomplished. No need to amend those laws or regulations was identified through that review.

Question: 8.C. How does the VA respond to inquiries from spouses and former spouses for information about the HIV status of VA patients?

Answer: The VA does not release medical information about individuals without their authorization. In practice, spouses and former spouses may be counseled to discuss their concerns with the patient. If the patient does not wish to reveal their HIV status and the contact feels he/she may have been put at risk, it appears to be good advice to recommend that they seek testing to determine their own HIV status.

Question: 8.D. What advice would you have for the VA medical center that is treating a recently divorced patient for ARC or AIDS and has received an inquiry from his ex-wife who asks whether the patient is or is not infected with HIV? Assume that the patient, contrary to his ex-wife's assertions, denies having engaged in sexual activity with his ex-wife since 1979 and withholds prermission for release of any information to her.

Answer: The advice would be the same:

1) Do not release or reveal medical information about the patient without authorization.

2) Recommend that the person making the inquiry discuss it with the patient. In any case, if the person making the inquiry felt concerned about his/her exposure, HIV testing should be sought.

Question: 8.E. In the same situation, assume that the patient does not deny having had sex with his ex-wife, but that the State involved does not have a contact notification system and the patient withholds consent to disclosure. What would you advise?

Answer: The advice would be the same. It should be noted that the involved medical staff is encouraged to work with the patient to deal with the issue of discussing his/her HIV status with significant others.

Question: 9. The Centers for Disease Control has issued guidelines regarding precautions that health-care workers should take to avoid exposure to the HIV virus.

9.A. Do you believe that health care workers should adhere to those guidelines as a matter of course, that is, in treating all patients?

Answer: It is becoming increasingly apparent that health care workers must consider all blood and body fluids potentially infective. This concept goes beyond CDC's current guidelines and current practice, however. The AIDS Working Group, established July 7, 1987, will be looking at the feasibility of instituting a comprehensive blood and body fluids isolation system of infection control in the VA.

Question: 9.B. Is this VA policy? Please provide copies of any circular or other guidance on this.

Answer: VA policy is consistent with the guidance provided by CDC at this time. This was disseminated via Circular 10-86-7 and is being reinforced by a circular now in the concurrence process. Copies of these two documents are attached.

Question: 10. In your written testimony you stated that 30,500 VA staff participated in education and training programs regarding AIDS in FY 1985. Please provide a breakdown describing briefly the programs involved and the categories of personnel who participated?

Answer: Examples of the kinds of programs offered included:

- AIDS/Kaposi Sarcoma: The Disease;
- Update on AIDS;
- Infection Control Update: AIDS;
- Properties of HTLV III;
- AIDS Update: Escalating Epidemic;
- Infection Control in Dental Practice;
- Nursing Care of Patients with AIDS;
- Isolation Guidelines and AIDS; and
- AIDS - Cause of the Disease - Patient Care Complications.

The programs generally dealt with several common issues: general information/education; diagnosis and treatment; and infection control.

The Office of Academic Affairs cannot provide an exact break-down for the categories of personnel who participated in AIDS training programs in FY 1985. However, we can estimate that approximately 50% of the participants were nurses, and the remaining 50% included physicians, dentists, associated health, and administrative staff.

Question: 11.A. Please describe in detail the VA's patient health education efforts regarding AIDS, particularly those targeted to groups at higher risk of developing the disease.

Answer: The 10 VA medical centers currently with the highest number of AIDS cases reported patient and family education activities in the topics listed below. This information is available to inpatients, outpatients, veterans in the community through VA Health Fairs as well as VA staff participating in community activities including community nursing homes, volunteers, families and significant others, recovering drug abuse patients, worried well (exposed to virus and/or HIV positive), and Zidovudine (formerly called ATZ) Drug Protocol participants.

The Mental Health and Behavioral Sciences Service is preparing a program guide entitled "Mental Health Issues Regarding AIDS." The program guide will draw from ongoing programs in several VA medical centers and similar programs in NIDA. It will address AIDS patient education as well as staff approaches to AIDS patients.

The Office of Academic Affairs (OAA) is establishing a comprehensive VA-wide AIDS Patient and Family Education Program. By the end of July, OAA will provide a profile of VA medical centers (VAMCs) AIDS Patient and Family Education activities and programs. This assessment will include program components, target audiences, print and non-print materials supporting educational activities, and the name of contact person by VAMCs and will provide the information necessary to assist those VAMCs that need help in developing effective patient health education (PHE) programs related to the following information:

- HIV screening and/or results
- Confidentiality and privacy of individual infected with AIDS
- Cause of AIDS
- Major avenues of transmission
- Methods to prevent spread of AIDS
- Difference in "high risk" and "low risk" activities
- Differences between infected with HIV virus but asymptomatic, AIDS-Related Complex (ARC), and AIDS
- Treatment of AIDS
- AIDS support groups
- AIDS as public health issue and impact on society
- Followup and availability of outreach program services such as housing, shopping, transportation, cleaning, cooking, finance, job counseling, emotional support, Testing Centers for family and significant others, home care, barbers, legal issues, wills, etc.
- Look Back Program related to blood transfusions
- Principles of infection control; skills in home care for care givers
- Clinical Drug Trial Programs

During July, the national Patient Health Education Conference Call will focus on AIDS patient and family education activities and programs. This conference call is directed to all VAMCs and will highlight effective PHE activities and programs.

In addition, the OAA conducts monthly bibliographic citation searches on AIDS and distributes this information to Regional Medical Education Centers (RMECs), Cooperative Health Manpower Education Programs (CHEPs), and chairpersons of VAMC PHE Committees. A computer search for audiovisuals related to AIDS has been conducted and distributed to RMECs.

Question: 11.B.(i) To whom were the 90,000 copies of the Surgeon General's report (noted in your May 21 testimony) distributed?

Answer: The Surgeon General's Report on Acquired Immune Deficiency Syndrome was distributed the first two weeks of January 1987 to VA Central Office Departments of Medicine and Surgery and Veterans Benefits, Regional Directors, Medical District Directors, VA Medical Centers Activities, Domiciliary, Outpatient Clinics, Regional Offices with Outpatient Clinics, Canteen Service Finance Offices, Prosthetic Center in Washington, D.C., Continuing Education Field Units, and the Veterans Service Organizations.

Question: 11.B.(ii) What was the cost of that distribution?

Answer: The Department of Medicine and Surgery acquired the Department of Health and Human Services' negatives for the Surgeon General's Report on AIDS and printed 90,000 copies for $14,233 or 15.8¢ per copy.

Question: 12. In your testimony, you mention that one of the purposes of the Department of Defense/VA Working Group is to ensure the smooth transfer of patients with AIDS from the military to the VA health care system. What is the current procedure?

Answer: The Armed Services Medical Regulating Office (ASMRO) functions as the clearing house for the transfer of all AIDS patients from military to VA health care systems. That office initiates a teletype containing various patient identification data to include diagnosis and other pre-admission information to a selected VA medical care facility nearest the service persons place of residence. The receiving VA medical care facility responds to the ASMRO regarding the availability of a bed and an admission date agreeable to both attending physicians. Once all these preliminaries are arranged, the ASMRO arranges all the necessary transportation to facilitate the transfer.

Question: 13. On page 13 of the Department of Defense's testimony, with respect to follow-up efforts to reach the sexual contacts, the DOD states that it generally provides local civilian health authorities with the names of sexual contacts of personnel identified as infected with the HIV who are not eligible for military health care. The DOD further testified that the anonymity of the service member is maintained "unless reporting is required by the health jurisdiction."

13.A. What policy do you follow in this respect?

Answer: The VA currently does not release personal or medical information about individual patients without authorization from the patient.

Question: 13.B. What would be your views with regard to the adoption of a federal policy of protecting anonymity in all cases?

Answer: It is unclear exactly what local civilian health authorities do with the names of people identified as sexual contacts of personnel identified as infected with HIV or whether this practice results in any benefit. The adoption of a federal policy of protecting the anonymity of the infected person only addresses one potential abuse of this type of reporting. It appears that a federal policy may be premature.

Question: 13.C. Please obtain and provide for the record the VA General Counsel's opinion on the issue of whether a VA policy directive protecting the veteran's anonymity could lawfully override a state or local requirement of disclosure.

Answer: It has long been held by the VA that where Federal law and state law, affecting Agency functions, are in conflict, Federal law is supreme. The VA's authority for identity disclosure for public health purposes is found in 38 U.S.C. 3301(f)(2). Where state law requires state and local medical facilities to disclose identity information, if all the requirements of section 3301(f)(2) are met by the state, then the VA would have discretionary authority to comply with the state law, but would not be compelled to comply therewith.

Question: 14. How much has the VA spent on conducting HIV antibody screening tests? How much does the VA anticipate spending of this purpose in FY 1988?

Answer: There is no way of determining how much the VA has spent conducting HIV screening tests since the VA has not encouraged screening except of the blood supply and there are no centralized records of either tests done or the costs. HIV tests have always been considered clinical tests which are to be ordered when clinically indicated. A survey of the extent of HIV testing in the VA is being developed with results expected in October 1987. The VA is beginning an expanded program of HIV testing which is expected to cost approximately 12 million dollars in FY 88.

Question: 15.A. What are the costs per case of drug testing and of follow-up where results are positive, and in each instance the cost of accompanying counseling?

Answer: After fourteen years of highly specialized toxicology testing on VA patients at our Memphis Special Reference Laboratory, we have determined that our costs for testing for a broad spectrum of drugs is $10 per patient. Screening for only opium, coccaine and marajuana costs $7 per patient. Each follow-up screen costs $10, when results are positive. The cost of accompanying counseling for patients is absorbed in the costs for methadone and non-methadone drug treatment programs.

Question: 15.B. In what percentage of cases, in your experience, are follow-up tests needed?

Answer: VA's Special Reference Laboratory for Toxicology at Memphis has performed toxicology tests for methadone and non-methadone drug programs at the rate of 750 specimens a month for the past fourteen years. The rate of confirmation is 20% in methadone addicted patients and 15% in non-methadone addicted patients. Other patients tested are those seen in emergency rooms for suspected drug abuse, and the confirmation rate in this group is 30-35%. Very few VA employee specimens are submitted to Memphis (2-3 a month) from other VA medical centers, and these are from employees who are highly suspect for drug use. The confirmation rate in this group is 40%.

Veterans Administration
Department of Medicine and Surgery
Washington, D.C. 20420

Circular 10-87-

DRAFT

TO: Regional Directors; Medical District Directors; Director, VA Medical Center Activities, Domiciliary, Outpatient Clinics, and Regional Offices with Outpatient Clinics

SUBJ: Prevention of Transmission of Infection with Human Immunodeficiency Virus (HIV) in the Work Place

1. PURPOSE: This DM&S Circular is a revision of DM&S Circular 10-86-7, dated January 24, 1986. It will not be incorporated into a manual at this time because changes in the recommendations for prevention of transmission are anticipated as the knowledge of AIDS and HIV infection increases.

2. POLICY: The VA has an infection control program at each facility to safeguard patients and employees against infections which are acquired in the facility or brought into the facility from the community. The Centers for Disease Control regularly publish guidance and recommendations concerning infection control which are covered in the medical literature and Morbidity and Mortality Weekly Report (MMWR). All local infection control policies must address AIDS and HIV infection.

3. ACTION: The recent publication in MMWR of HIV infections in three health care workers with non-needle-stick exposures to blood of infected patients reemphasizes the need for health care workers to adhere rigorously to existing infection control recommendations for minimizing the risk of exposure to blood and body fluids of all patients. As stated in the MMWR report, it is unlikely that routine serologic testing for HIV in all hospitalized patients would have had any affect on the exposures reported. It is essential that facilities make the appropriate protective supplies readily available to all employees when there is a possibility of exposure to HIV.

a. As previously recommended, routine precautions must be followed when there is a possibility of exposure to blood or other body fluids. The anticipated exposure may require gloves alone (e.g., when placing an intravascular catheter or handling items soiled with blood or equipment contaminated with blood or other body fluids). Procedures involving more extensive contact with blood or potentially infective body fluids (e.g. some dental or endoscopic procedures or postmortem examinations) may require gloves, gowns, masks, and eye coverings. Hands and other contaminated skin surfaces should be washed thoroughly and immediately if accidentally contaminated with blood. These precautions deserve particular emphasis in emergency care settings in which the risk of blood exposure is increased and the infectious status of the patient is usually unknown.

b. Previous recommendations have emphasized management of parenteral and mucous membrane exposures of health-care workers. In addition, health-care workers who are involved in incidents that result in cutaneous exposures involving large amounts of blood or prolonged contact with blood - especially when the exposed skin is chapped, abraded, or afflicted with dermatitis - should follow these same recommendations.

DRAFT

Circular 10-87-

c. Serologic testing and appropriate counseling should be available to all health-care workers who are concerned that they may have been infected with HIV.

d. Questions may be referred to the Program Chief, Pulmonary and Infectious Diseases, VA Central Office, Medical Service (111), FTS 373-2450.

4. REFERENCES:

a. CDC Update: Human Immunodeficiency Virus Infections in Health Care Workers Exposed to Blood of Infected Patients. MMWR 1987; 36:2285-289.

b. CDC Summary: Recommendations for preventing transmission of infection with human T-lymphotropic virus type 111/lymphadenopathy associated virus in the workplace. MMWR 1985; 34:P 681-5, 691-5.

c. CDC Recommendations for preventing transmission of infection with human T-lymphotropic virus type 111/lymphadenopathy-associated virus during invasive procedures. MMWR 1986; 35:221-3.

d. CDC Recommended infection-control practices for dentistry. MMWR 1986; 35:237-42.

5. RESCISSIONS: DM&S Circular 10-86-7. This DM&S circular will be rescinded

6. FOLLOW-UP RESPONSIBILITY: Assistant Chief Medical Director for Clinical Affairs (111).

JOHN A. GRONVALL, M.D.
Chief Medical Director

January 24, 1986

TELEGRAPHIC MESSAGE

NAME OF AGENCY
VETERANS ADMINISTRATION

PRECEDENCE
PRIORITY
ACTION
INFO

SECURITY CLASSIFICATION
files

ACCOUNTING CLASSIFICATION

DATE PREPARED
12/12/85

FILE

FOR INFORMATION CALL

NAME
T. Brown

PHONE NUMBER
X3097

TYPE OF MESSAGE
☐ SINGLE ☐ BOOK ☒ MULTIPLE ADDRESS

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MESSAGE TO BE TRANSMITTED (Use double spacing and all capital letters)

TO:

AIDS -

DIRECTORS, ALVAMC AND REGIONAL OFFICES WITH OUTPATIENT CLINICS, ALVAMOD, (REGIONAL DIRECTORS)

00/ THIS IS DM&S CIRCULAR 10-86-7 (DTD: 1/24/86)

SUBJ: RECOMMENDATIONS FOR PREVENTING TRANSMISSION OF INFECTION WITH HUMAN T-LYMPHOTROPIC VIRUS TYPE III/LYMPHADENOPATHY - ASSOCIATED VIRUS (HTLV-III/LAV) IN THE WORKPLACE

1. THE PURPOSE OF THIS CIRCULAR IS TO CALL ATTENTION TO THE INFORMATION AND RECOMMENDATIONS CONTAINED IN THE NOVEMBER 15, 1985, MMWR (CDC MORBIDITY AND MORTALITY REPORT/VOL. 34/NO. 45/ PP 681-694).

2. DM&S SUPPORTS THESE RECOMMENDATIONS WHICH SHOULD BE INCORPORATED INTO LOCAL POLICY CONCERNING HTLV-III/LAV INFECTION AND AIDS.

3. THIS DM&S CIRCULAR EXPIRES DECEMBER 31, 1986. 111/11

John A Gronvall M.D.

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ADVANCE CY

WRITTEN QUESTIONS FROM SENATOR GRAHAM TO THE VETERANS' ADMINISTRATION AND THE RESPONSES

Question: 1. Is the Veterans Administration developing home health care programs, respite care programs, and care giver assistance programs in order to help reduce the acute and chronic medical costs of patient care and improve the quality of life for the AIDS victim?

Answer: The Veterans Administration has existing Hospital Based Home Care Programs at 68 VA medical centers. A number of these programs in major metropolitan areas have been treating AIDS patients, when home care is clinically indicated and a caregiver is available. The VA is developing a Respite Care Program under the authority of Public Law 99-576. AIDS patients will be considered for this program when the caregiver needs respite and the veteran meets existing eligibility requirements. The VA has no authority to directly provide caregiver assistance services in the home. These services are normally provided by community-based organizations and VA staff will make the necessary referrals for individual patients.

Question: 2. What efforts are being made on the part of the Veterans Administration to help coordinate chronic medical services with individual State's social service programs in order to reduce bureaucratic frustration of the AIDS patient?

Answer: At VA medical centers that are treating a significant number of AIDS patients, major efforts are underway to ensure that services that will be needed following discharge from the hospital are arranged for through the VA, State and local agencies. For an individual patient, an assessment is completed and a plan developed that addresses housing, finances, and support systems. These interventions require a great deal of coordination with community agencies. At an organizational level, VA health care professionals are working closely with community groups, lending their technical expertise, as communities develop programs to assist AIDS patients.

Question: 3. Is the Veterans Administration developing alternative housing programs, other than acute care beds or nursing home beds for the socially dependent AIDS patient?

Answer: The VA provides care to AIDS patients who are ambulatory and do not need skilled nursing care, but do require a sheltered environment and minimal medical care, through the Domiciliary Program. The VA is examining the possibility of referring AIDS patients to the Community Residential Care Program. This program provides room, board, general supervision and assistance to veterans who cannot live independently because of a disability and do not have a family to provide the needed care. The VA has no authority to directly provide "housing" to any group of patients.

WRITTEN QUESTIONS FROM SENATOR MURKOWSKI TO THE VETERANS' ADMINISTRATION AND THE RESPONSES

Question: 1. What efforts are made by the VA to coordinate research efforts with HHS, DOD and other Federal Agencies?

Answer: Coordination, in the sense of collaboration, is encouraged for all VA investigators. Many VA principal investigators have effectively interfaced with other researchers from the various federal agencies. In addition, members of the medical research peer review boards, which were established to provide scientific review of all proposals, often serve on similar review panels for other agencies. Medical Research Service encourages membership with NIH study groups by nominating and supporting VA investigators who are willing to serve. A very large number of the VA's investigators also serve as reviewers for refereed publications.

The VA is unique in its support of clinically oriented research and has emerged as a world leader in clinically oriented research, and is looked to by other federal agencies and industry to undertake important clinical studies. All VA research is carefully evaluated by outside national experts to assure that funded studies are unique and will advance medical knowledge and patient care.

Question: 2. Please provide the Committee with a list of all past, ongoing, or planned VA AIDS research projects (including cost information).

Answer: The following table shows funding and number of projects for AIDS related research since 1984. Attached is a list of all past and ongoing AIDs projects.

		VA	Extra VA
FY 1984	24 projects	$ 661,099	$ 948,746
FY 1985	34 projects	986,898	1,531,074
FY 1986	49 projects	897,603	2,291,702
FY 1987 estimate (1/1/87)		2,086,599	3,700,000

Question: 3. What criteria is used to determine which research proposals receive funding?

Answer: Research proposals are submitted to Medical and Prosthetic Research in VA Central Office where they are assigned to a relevant board consisting of a National Committee of peers for review for scientific merit. Only those programs which are deemed meritorious by these boards are considered for funding. The criteria used by these boards include: 1) an evaluation of the importance or significance of the study to a specific field of science, 2) the novelty and originality of the study, 3) the soundness and feasibility of experimental design, 4) adequacy of the methodology, 5) adequacy of institutional resources and staff, 6) the competence and level of productivity of the investigator(s), 7) the appropriateness of the budget and duration of funding and 8) evaluation of human and animal ethical concerns and biohazards.

Question: 3.A. Who is eligible to receive this funding?

Answer: Medical Research Service has a published policy which states that only staff who have either 5/8's salary paid by the VA or who spend 5/8's of their time within the VA Medical Center may submit proposals for possible funding.

Question: 3.B. Are there specific requirements that must be met in order for funding to be continued?

Answer: Merit Review Board approval includes a recommendation for duration which currently averages three years. At the end of the project approval period the entire process of a national review for scientific merit is repeated. Thus, the requirement for continued funding is to resubmit an approvable research project.

Question: 4. What components are essential for an effective AIDS prevention and education program? What would such a program cost?

Answer: There are basic elements for an curriculum of education about AIDS. They are:

- the nature of the diseases caused by Human Immunodeficiency Virus (HIV) including AIDS and ARC.
- the meaning of infection with HIV
- methods by which the virus can be transmitted (as well as actions which do not lead to transmission)
- the meaning of an HIV test
- ways a person can protect oneself and others from infection

Education is the basis of prevention since no vaccine or immunization exists but the means of transmission of the virus is well known. The majority of cases of AIDS result from specific behaviors which can be modified. The amount and nature of the education aimed specifically at prevention depends on the target audience and the degree of their risk.

For veterans who do not use IV drugs and have mutually monogamous sexual relationships, the Surgeon General's Report on AIDS is an excellent tool and costs the VA 16¢ per copy to reproduce.

For those veterans who are homosexual or bisexual, counseling and education needs to be directed at understanding how their sexual behavior puts them at special risk and how to protect themselves and their partners. This is often most effective when linked to HIV testing. Then special efforts need to be directed at those who are already positive.

For IV drug users, the principles are the same but the content of the education will be different. An important element of prevention for IV drug users is treatment, such as Methadone maintanence, for their drug addiction. It is reported in some metropolitan areas that fear of AIDS has led addicts to seek treatment in record numbers.

The VA does not know how much a comprehensive education and prevention program would cost. However, it is estimated that an HIV testing and counselling program for 700,000 veteran patients at high risk of AIDS would cost $12,242,000.

Question: 5. Does the VA have an AIDS Hotline?

A. If so, please describe that program?

Answer: The VA does not have an AIDS Hotline.

Question: 5.B. If not, would one be useful?

Answer: We do not feel that a central AIDS Hotline would be useful at this time. Questions tend to be highly individualized and are best answered personally at the local facility providing care. Veterans and staff, also have access to community Hotlines. However, we will evaluate the need for such a service in the future.

JUL 29, 1987 VETERANS ADMINISTRATION PAGE 1
RESEARCH AND DEVELOPMENT INFORMATION SYSTEM
AIDS RESEARCH-ALL PROJECTS

Polyneuropathy Associated with AIDS: Evidence for Autoimmune Pathogenesis
BAILEY, RONALD O., M.D. 500 ALBANY, NY
LAST REPORT, INITIAL 04/86

Cerebral Herpetic Infections in the Acquired Immunodeficiency Syndrome
KOEPPEN, ARNULF H. W., M.D. 500 ALBANY, NY
LAST REPORT, FINAL 03/87

Uncontrolled clinical trial of long term safety of AZT
SMITH, RAYMOND P., M.D. 500 ALBANY, NY
LAST REPORT, INITIAL 03/87

BACTERIOLOGIC AND IMMUNE STUDIES IN WHIPPLE'S DISEASE
DOBBINS, WILLIAM O., III, M.D. 506 ANN ARBOR, MI
LAST REPORT, FINAL 03/86

Disease and Immune Competence in Homosexual Men
RIMLAND, DAVID, M.D. 508 DECATUR, GA
LAST REPORT, FINAL 07/84

Structure-activity relationship of anti-HLTV-III/LAV Compounds
SCHINAZI, RAYMOND F., Ph.D. 508 DECATUR, GA
LAST REPORT, INITIAL 07/86

Retrovirus Induced Changes in Neural Cell Membrane Function
BILELLO, JOHN A., Ph.D. 512 BALTIMORE, MD
LAST REPORT, PROGRESS 02/86

Development of Models Infected with Retroviruses for Testing of Anti-Viral Agents
BILELLO, JOHN A., Ph.D. 512 BALTIMORE, MD
LAST REPORT, INITIAL 02/86

Retrovirus Paralysis and Lymphoma in Adult Mice
HOFFMAN, PAUL M., M.D. 512 BALTIMORE, MD
LAST REPORT, PROGRESS 01/85

The Natural History of Acquired Immune Deficiency Syndrome (AIDS) in Homosexual Men
PHAIR, JOHN P., M.D. 535 CHICAGO, (LAKESIDE), IL
LAST REPORT, PROGRESS 07/86

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JUL 29, 1987              VETERANS ADMINISTRATION                 PAGE     2
                  RESEARCH AND DEVELOPMENT INFORMATION SYSTEM
                           AIDS RESEARCH-ALL PROJECTS


  Infectious Etiology of Acquired Immune Deficiency Syndrome
PHAIR, JOHN P., M.D.                         535 CHICAGO, (LAKESIDE), IL
                    LAST REPORT, FINAL             06/85


  Pathogenesis of Lung Injury due to Pneumocystis Carinii
SMITH, LEWIS J., M.D.                        535 CHICAGO, (LAKESIDE), IL
                    LAST REPORT, FINAL             09/86


  ICC 84M1 - Phase II Evaluation of Human Lymphoblastoid Interferon
  (WELLFERON) in Kaposi's Sarcoma
WINTER, JANE N., M.D.                        535 CHICAGO, (LAKESIDE), IL
                    LAST REPORT, FINAL             11/85


  Histocompatibility, viral and immunogenetic factors in cirrhosis
SCHIFF, EUGENE R., M.D.                      546 MIAMI, FL
                    LAST REPORT, PROGRESS 07/86


  Association of Blood Product Use with Immune Function Changes: Relation to
  AIDS
SCHIFF, EUGENE R., M.D.                      546 MIAMI, FL
                    LAST REPORT, INITIAL  07/86


  Uncontrolled Clinical Trial of the Long Term Safety of AZT
SUNSTRUM, JAMES, M.D.                        553 ALLEN PARK, MI
                    LAST REPORT, INITIAL  01/87


  Tests for Isoprecipitins in sera of patients with AIDS  (title change)
BLASER, MARTIN, M.D.                         554 DENVER, CO
                    LAST REPORT, FINAL             03/87


  Biochemical characterization of human immune neutropenias
CURRIE, MARK S., M.D.                        558 DURHAM, NC
                    LAST REPORT, INITIAL  03/87


  Treatment of AIDS and AIDS-Related Complex: Part I. Treatment of patients
  with ARC
HAMILTON, JOHN D., M.D.                      558 DURHAM, NC
                    LAST REPORT, INITIAL  02/87
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Pathogenesis of Epstein-Barr Virus and Cytomegalovirus Infection
KLOTMAN, MARY E., M.D. 558 DURHAM, NC
LAST REPORT, INITIAL 01/86

HTLV-1 Sequences in Multiple Sclerosis
COOK, STUART D., M.D. 561 EAST ORANGE, NJ
LAST REPORT, INITIAL 05/86

Neurologic Manifestations of HTLV-III Infection
DOWLING, PETER, M.D. 561 EAST ORANGE, NJ
LAST REPORT, PROGRESS 06/87

Retrospective Study of Ketoconazole Efficacy
ENG, ROBERT H.K., M.D. 561 EAST ORANGE, NJ
LAST REPORT, FINAL 05/85

The Risk of Bacteremia in Patients with Acquired Immune Deficiency Syndrome
ENG, ROBERT H.K., M.D. 561 EAST ORANGE, NJ
LAST REPORT, PROGRESS 09/86

Adrenal Function in Patients with Acquired Immunodeficiency Syndrome
ENG, ROBERT H.K., M.D. 561 EAST ORANGE, NJ
LAST REPORT, FINAL 04/85

Open, noncomparative study of Fluconazole for treatment of fungal diseases in patients with acquired immunodeficiency syndrome
ENG, ROBERT H.K., M.D. 561 EAST ORANGE, NJ
LAST REPORT, INITIAL 07/86

Consequences of HTLV-III Infection for IV Drug Abusers
DORUS, WALTER, M.D. 578 HINES, IL
LAST REPORT, PROGRESS 02/87

A Model of Human T-Cell Differentiation Seen in T-Cell Neoplasia
MINOWADA, JUN, M.D., Ph.D. 578 HINES, IL
LAST REPORT, FINAL 04/87

Spontaneous and Induced Activation of Silent Retroviral Oncogenes
TUREK, LUBOMIR P., M.D. 584 IOWA CITY, IA
LAST REPORT, PROGRESS 12/86

Determinants of Mucosal Colonization and Infection with Candida in HTLV-III Related Syndromes
SEGAL, GARY P., M.D. 600 LONG BEACH, CA
LAST REPORT, INITIAL 09/86

Cellular Pathogenesis of Central Nervous System Spongiform Degeneration
BROOKS, BENJAMIN R., M.D. 607 MADISON, WI
LAST REPORT, PROGRESS 03/85

In Vitro Transformation of Human Hematopoietic Stem Cells
MAUER, ALVIN M., M.D. 614 MEMPHIS, TN
LAST REPORT, PROGRESS 02/87

The Immune Response in Patients with Infections Due to Atypical Mycobacteria
EL-SADR, WAFAA M., M.D. 630 NEW YORK, NY
LAST REPORT, FINAL 12/84

Transmissibility of Acquired Immune Deficiency
EL-SADR, WAFAA M., M.D. 630 NEW YORK, NY
LAST REPORT, FINAL 12/84

Risk Factors for Acquired Immune Deficiency (AIDS) among Intravenous Drug Users
EL-SADR, WAFAA M., M.D. 630 NEW YORK, NY
LAST REPORT, FINAL 05/85

AIDS-Associated Pneumocystis carinii and Macrophages
SHEAR, HANNAH L., Ph.D. 630 NEW YORK, NY
LAST REPORT, INITIAL 09/85

AIDS-Associated Pneumocystis carinii and Macrophages in Rodents and Humans
SHEAR, HANNAH L., Ph.D. 630 NEW YORK, NY
LAST REPORT, INITIAL 09/85

Use of Ansamycin (LM-427)
SIMBERKOFF, MICHAEL S., M.D. 630 NEW YORK, NY
LAST REPORT, PROGRESS 12/84

Use of Clofazimine for M. Avium intracellulare infection
SIMBERKOFF, MICHAEL S., M.D. 630 NEW YORK, NY
LAST REPORT, PROGRESS 12/84

(Protocol BW-B759U-002) To Treat Bone Marrow Transplant, AIDS or Other Immunocompromised Patients with Cytomegalovirus, Pneumonitis & Retinitis
SIMBERKOFF, MICHAEL S., M.D. 630 NEW YORK, NY
LAST REPORT, INITIAL 01/85

HTLV-3 Antibody Testing
SIMBERKOFF, MICHAEL S., M.D. 630 NEW YORK, NY
LAST REPORT, INITIAL 02/85

Pathogenic Role of Hyperactive B Cells in AIDS
ZOLLA-PAZNER, SUSAN, Ph.D. 630 NEW YORK, NY
LAST REPORT, INITIAL 05/84

Phenotypic and Functional Characterization of Benign and Malignant B Cells in Patients with AIDS
ZOLLA-PAZNER, SUSAN, Ph.D. 630 NEW YORK, NY
LAST REPORT, INITIAL 05/84

Effect on Human B Cells of Derivatized Guanine Nucleosides
ZOLLA-PAZNER, SUSAN, Ph.D. 630 NEW YORK, NY
LAST REPORT, INITIAL 06/84

Infection with Human T-Cell Lymphotropic Virus Type III (HTLV-III) in Hemodialysis Patients and Hemodialysis Unit Staff at VAMC Northport
RUSH, THOMAS J., M.D. 632 NORTHPORT, NY
LAST REPORT, FINAL 01/87

Incidence of Antibodies to HTLV-III Following Cardiac Surgery in Patients Followed at the Salem VAMC
SCHLEUPNER, CHARLES JOHN, M.D. 658 SALEM, VA
LAST REPORT, INITIAL 10/86

Tumor Virus Vaccine: Tumor Antigens; Carbohydrates of Envelope (title change)
WRIGHT, STEPHEN E., M.D. 660 SALT LAKE CITY, UT
LAST REPORT, PROGRESS 12/86

Role of Immunospecific Receptors in Retrovirus Induced Leukemogenesis
MCGRATH, MICHAEL S., M.D. 662 SAN FRANCISCO, CA
LAST REPORT, FINAL 04/87

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  Lymphoid Follicle and Intestinal Epithelial Structure and Function
OWEN, ROBERT L., M.D.                          662 SAN FRANCISCO, CA
                    LAST REPORT, PROGRESS 04/87


  Clinical Trials in AIDS
ZIEGLER, JOHN L., M.D.                         662 SAN FRANCISCO, CA
                    LAST REPORT, INITIAL  10/86


  Retroviral Related Endogenous Cellular Oncogenes in Human Malignancy
COLLINS, STEVEN JAMES, M.D.                    663 SEATTLE, WA
                    LAST REPORT, FINAL              06/86


  Arthritis with Neutropenia and Excess Large Granular Lymphocytes
STARKEBAUM, GORDON A., M.D.                    663 SEATTLE, WA
                    LAST REPORT, PROGRESS 10/86


  Clofazimine for Treatment of M. Avium Intracellular Infections in Patients
  with AIDS
FIERER, JOSHUA, M.D.                           664 SAN DIEGO, CA
                    LAST REPORT, INITIAL  03/86


  Ansamycin for Treatment of M. Avium Intracellular Infections in Patients
  with AIDS
FIERER, JOSHUA, M.D.                           664 SAN DIEGO, CA
                    LAST REPORT, INITIAL  03/86


  Phase II Trial of AZT (Azidothmidine) for Patients with AIDS/ARC
RICHMAN, DOUGLAS D., M.D.                      664 SAN DIEGO, CA
                    LAST REPORT, INITIAL  03/86


  A Seroepidemiologic Study of alpha-HTLV Antibodies in Humans
POIESZ, BERNARD J., M.D.                       670 SYRACUSE, NY
                    LAST REPORT, PROGRESS 04/86


  Uncontrolled Clinical Trial of the Long Term Safety of Azidothymidine
SMITH, JEAN A., M.D.                           671 SAN ANTONIO, TX
                    LAST REPORT, INITIAL  03/87


  Ansamycin Therapy of M. Avium-Intracellulare Infections
GORDIN, FRED M., M.D.                          688 WASHINGTON, DC
                    LAST REPORT, PROGRESS 04/87
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A Survey of Hospital Staff's Knowledge, Emotional Reactions and Behavior Regarding AIDS Patients
GORDIN, FRED M., M.D. 688 WASHINGTON, DC
LAST REPORT, FINAL 12/86

Pancreatitis associated with AIDS
GORDIN, FRED M., M.D. 688 WASHINGTON, DC
LAST REPORT, INITIAL 06/86

Azidothymidine (AZT) in the treatment of persons with AIDS
GORDIN, FRED M., M.D. 688 WASHINGTON, DC
LAST REPORT, INITIAL 10/86

Anxiety, Depression and Coping in Patients with AIDS, ARC, and the "Worried Well"
GORDIN, FRED M., M.D. 688 WASHINGTON, DC
LAST REPORT, INITIAL 03/87

Anxiety, Depression and Coping in Patients with AIDS, ARC, and the "Worried Well"
MORIHISA, JOHN M., M.D. 688 WASHINGTON, DC
LAST REPORT, FINAL 03/87

HTLV Antibody Screening in Hospitalized Patients.
SCHECHTER, GERALDINE P., M.D. 688 WASHINGTON, DC
LAST REPORT, FINAL 11/86

Serologic analysis of CMV and HTLV-III antibody status
HSIUNG, GUEH-DJEN, Ph.D. 689 WEST HAVEN, CT
LAST REPORT, INITIAL 02/86

The local and systemic immune response in mixed viral/pneumocystis infection
MERRILL, WILLIAM W., M.D. 689 WEST HAVEN, CT
LAST REPORT, FINAL 03/86

Possible Causes of Unexplained Diarrhea in AIDS Patients
FINEGOLD, SYDNEY M., M.D. 691 WEST LOS ANGELES (WADSWORTH DIV
LAST REPORT, INITIAL 04/86

Stresses of Hospitalization in the AIDS Patient
HEFFERIN, ELIZABETH A., RN 691 WEST LOS ANGELES (WADSWORTH DIV
LAST REPORT, INITIAL 02/87

Acquired Immune Deficiency Syndrome in Hemophiliacs and Spouses
KREISS, JOAN, M.D. 691 WEST LOS ANGELES (WADSWORTH DIV
LAST REPORT, FINAL 02/84

Early Diagnosis of Lung Involvement in Individuals at Risk of Developing the Acquired Immune Deficiency Syndrome
LEHRMAN, STUART G., M.D. 691 WEST LOS ANGELES (WADSWORTH DIV
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VP16-213 for Treatment of Kaposi's Sarcoma
LICHTENSTEIN, ALAN K., M.D. 691 WEST LOS ANGELES (WADSWORTH DIV
LAST REPORT, PROGRESS 05/85

UCLA-Affiliated Hospitals Surveillance for Acquired Immune Deficiency Syndrome
MULLIGAN, MAURY E., M.D. 691 WEST LOS ANGELES (WADSWORTH DIV
LAST REPORT, PROGRESS 08/85

Neutrophil Function in Patients with AIDS
SOHNLE, PETER G., M.D. 695 MILWAUKEE, WI
LAST REPORT, FINAL 04/87

COPY #1 COMPLETED

WRITTEN QUESTIONS FROM SENATOR SIMPSON TO THE VETERANS' ADMINISTRATION AND THE RESPONSES

Question: 1. Dr. Gronvall, I'm a bit confused by a portion of your prepared testimony, and I would appreciate it if you would clear that up for me. On page 5 of your written testimony, you state that the cost per year to treat an AIDS patient in FY 1985 was estimated at $38,000. You then indicate that a "more recent" study set that cost at $24,000 a year. When was that more recent study done?

Answer: The estimate of the costs for FY 1985 were based on the findings of a survey done in 1985 of three VAMCS who had seen large numbers of patients and used basic per diem rates, outpatient visit costs, average lengths of stays, days-in ICU and numbers of outpatient visits. The $24,000 estimate was based on the experience in eleven VA medical centers in FY 1986 done in the spring of 1987.

Question: 2. In the next paragraph you indicate that the cost to treat an AIDS patient has decreased about 20% since FY 1985. And that you are now using $20,000 as the estimate of cost per patient per year for FY 1987. If the cost estimate in FY 1985 was $38,000, and the cost has decreased by 20% since that time, why are you using $20,000 as your estimate rather than $30,400, which is a decrease of 20% since your 1985 figures?

Answer: The 20% was an estimate based on the observations by clinicians in the field reflecting on the way recent changes in medical practice related to AIDS would appear to affect costs. It must be emphasized that cost estimates to date are very "soft" data because the VA does not have an individual patient cost accounting system, we cannot determine the cost to treat any one individual or group of individuals.

Question: 3. Are you satisfied that $20,000 is an adequate estimate of the current costs per year per patient.

Answer: No, that is why I have appointed a special Task Force headed by Mr. Sandy Garfunkel, the Director of VAMC New York, to study costs of care for AIDS and recommend a valid system of reimbursement for medical centers treating these very complex patients.

Question: 4. Dr. Gronvall you indicated that supplemental funding has been provided for VA facilities that have seen more than 15 cases in FY 1987. How has that supplemental funding been provided, and in what amount?

Answer: Supplemental funding from the Medical Care Appropriation available to the Department was provided to the following VA medical centers:

VAMC Brooklyn	$ 328,300
VAMC New York	1,023,100
VAMC East Orange	267,800
VAMC Miami	743,000
VAMC West Los Angeles	786,200
VAMC San Francisco	466,500
VAMC Houston	380,100